

9/27/02 11:50 am

Notification Tracking Sheet

=====
Bp number: 02-263-15n
=====

App number: 2002-829XRAB
Received: 9/20/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/20/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 9/19/02
End movement: 9/19/03
Begin release: 9/19/02
End release: 9/19/03
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[9/27/02]
2. <input type="checkbox"/> Review by biotechnologist OR120018_BR_009815	[<i>UM</i>]*	[10/1/02]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[<i>K&L</i>]	[10/2/02]*

4. [] State response

	O/d	Loc	Site	Reg			
Interstate	*Dest*	CA	*	*WR	*	[]
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Orig*	CA	*	*WR	*	[]
Interstate	*Orig*	MO	*	*SCR	*	[]
Release	*	*CA	*	1*WR	*	[]

5. [✓] Enter genes into database [apt] [10/1/02]
6. [✓] Letter of acknowledgement denial/withdraw [KLD] [10/10/02]*
7. [✓] Enter final data into database [KLD] [10/16/02]
8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

MONSANTO



CONFIDENTIAL

Monsanto Reference ID
2002-829XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63108

<http://www.monsanto.com>

Permit Unit

September 19, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number

02-263-15n

2. Application Reference Number 2002-829XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis, MO 63108

OR120018_BR

4. Duration of Introduction

Interstate Movement and Release

September 19, 2002 - September 19, 2003

5. Recipient

Wheat, *Triticum aestivum*

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, WPD 926, WPB 936, Conan, McNeal

CONFIDENTIAL

Monsanto Reference ID

2002-829XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2002-829XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction

20,000 Ship up to 20,000 pounds wheat seed to and from each location.

ORIGIN:

CA, MO

DESTINATION:

CA, MO

Ship From:

CA

OR120018_BR_009821

*

(b) (4)

Imperial County/Province, CA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

* (b) (4) St. Louis County/Province, MO, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

Ship To:

CA

* (b) (4) Imperial County/Province, CA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

MO

CONFIDENTIAL

Monsanto Reference ID
2002-829XRAB

* [REDACTED] (b) (4) St. Louis County/Province, MO, USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

OR120018_BR_009823

CONFIDENTIAL

Monsanto Reference ID
2002-829XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA(1)

CA

[(b) (4) Imperial County/Province, CA, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) CA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

OR120018_BR_009825

MONSANTO



CONFIDENTIAL

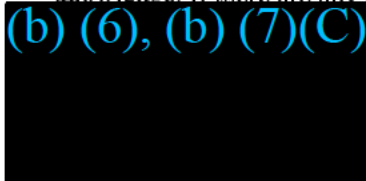
Monsanto Reference ID
2002-829XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 19, 2002

OR120018_BR_009827

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.* , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every

subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expensive and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

OR120018_BR_009834

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2002-829XRAB

Permit Unit

September 19, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-263-15n

1. USDA Reference Number

2. Application Reference Number 2002-829XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Monsanto Company

700 Chesterfield Parkway North

OR120118_BR_

Email

(b) (6), (b) (7)(C)

@monsanto.com

4. Duration of Introduction

Interstate Movement and Release September 19, 2002 - September 19, 2003

5. Recipient

Wheat, *Triticum aestivum*

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, WPD 926, WPB 936, Conan, McNeal

CBI-DELETED

Monsanto Reference ID
2002-829XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

OR120018_BR_009837

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2002-829XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction

20,000 Ship up to 20,000 pounds wheat seed to and from each location.

ORIGIN:

CA, MO

DESTINATION:

CA, MO

Ship From:

CA

OR120018_BR_009839

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

Ship To:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID
2002-829XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA(1)

CA

[CBI Deleted] -- Imperial County/Province, CA, USA, 10 acres.

OR120018_BR_009841

MONSANTO



CBI-DELETED

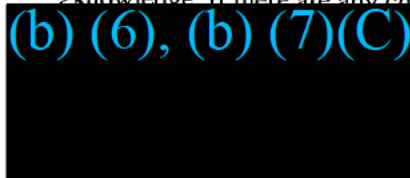
Monsanto Reference ID
2002-829XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 19, 2002

OR120018_BR_009843

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 27, 2002

Dear Ms. Hass:

Enclosed is notification 02-263-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-263-15n	Applicant #:	2002-829XRAB
Received:	September 20, 2002	Effective:	October 20, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. **OR120018_BR_009845**

Sincerely,

|S|
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009846

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 27, 2002

Dear Mr. Brown:

Enclosed is notification 02-263-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-263-15n	Applicant #:	2002-829XRAB
Received:	September 20, 2002	Effective:	October 20, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.12 (c) that you provide an acknowledgement within 30 days of receipt.

02-263-15n-009847

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009848



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 27, 2002

Dear Ms. Hass:

Enclosed is notification 02-263-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-263-15n
Received: September 20, 2002
Institution: Monsanto
Interstate destination: CA MO
Release destination: CA

Applicant #: 2002-829XRAB
Effective: October 20, 2002
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

OR120018_BR_009849

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen S. Brown (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 4, 2002

State: California

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009850

OCT 7 2002

California Quarantine Requirements
USDA/APHIS Biotechnology Notification No. 02-2263-15N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Missouri shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.

OR120018_BR_009851

OR120018_BR_009852



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 27, 2002

Dear Mr. Brown:

Enclosed is notification 02-263-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-263-15n	Applicant #:	2002-829XRAB
Received:	September 20, 2002	Effective:	October 20, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

OR120018 BR 009853

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Bown

Signature: _____

(b) (6), (b) (7)(C)

Date: 10/07/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

OR120018_BR_009854

An Equal Opportunity Employer

OCT 8 2002

P.04/21 573751005

DEPT OF AGRICULTURE

OCT-08-2002 15:13

October 10, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 20, 2002.

Interstate movement and Release
Notification no. 02-263-15n (2002-829XRAB)
Regulated article - Wheat
Destinations - California, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. **CP 120912 BR 009855** Packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
File number 02-263-15n

OR120018_BR_009856

California Quarantine Requirements
USDA/APHIS Biotechnology Notification No. 02-2263-15N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Missouri shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.

OR120018_BR_009857

OR120018_BR_009858

Confirmation Report-Memory Send

Time : Oct-11-02 04:46pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 086
Date : Oct-11 04:45pm
To : 916367377085
Document Pages : 02
Start time : Oct-11 04:45pm
End time : Oct-11 04:46pm
Pages sent : 02

Job number : 086

*** SEND SUCCESSFUL ***



Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

OR120018_BR_009859 October 10, 2002

(b) (6), (b) (7)(C)
Montano Company
700 Chesterfield Pkwy N

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 20, 2002.

Interstate movement and Release
Notification no. 02-263-15n (2002-829XRAS)
Regulated article - Wheat
Destinations - California, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009860

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-263-15n Monsanto #2002-829XRAB

January 7, 2004

Biotech Field Compliance Team
Monsanto Company

Location

2147316881

County

Imperial

State

CA

Imperial County/CA (2147316881)

(b) (4)

(b) (4)

ad
1/8/09

(b) (4)

OR120018_BR_009863

USDA# 02-263-15n

Page 2 of 2

Monsanto #2002-829XRAB

OR120018_BR_009864

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

OR120018_BR_009865

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have consistently found that information which is developed in the course of commercial development is a trade secret.

request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_009867

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-263-15n Monsanto #2002-829XRAB

January 7, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147316881	Imperial	CA

Imperial County/CA (2147316881)

Planting Date: 11/15/2002

Harvest Date: 05/21/2003

Destruct Date: 06/01/2003

Vector Constructs/Line Numbers Planted: [CBI Deleted] **QB120018 BR 009869**

Purpose of Field Trial: [CBI Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/17/03 12:20 pm

Notification Tracking Sheet

=====
Bp number: 03-015-07n
=====

App number: 2003-18XRAB
Received: 1/15/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/03
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement: 2/12/03
End movement: 2/12/04
Begin release: 2/12/03
End release: 2/12/04
Acre: 20.00
CBI status: CBI

Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**

Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [1/22/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>JMC</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLN</i>] | [1/23/03]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Interstate	*Orig*SD	*	*SCR *
Release	* *SD	*	2*SCR *

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLN</i>] | [2/6/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLN</i>] | [2/7/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

OR120018_BR_009871

*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>**Monsanto Reference ID**
2003-18XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-07n

1. USDA Reference Number**2. Application Reference Number** 2003-18XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite.

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Monsanto Reference ID

2003-18XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-18XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From/Ship To:

KS

*[(b) (4)] Harvey County/Province, KS (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

MT

*[(b) (4)] Gallatin County/Province, MT (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2003-18XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

* (b) (4) Spink County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Brown County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Minnehaha County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Brookings
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Brookings County/Province, SD,
(b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A, (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Codrington
County/Province, SD, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2003-18XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A.,
]-CBI

CONFIDENTIAL

Monsanto Reference ID
2003-18XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[(b) (4) Spink County/Province, SD (b) (4) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

[(b) (4) Codington
County/Province, SD, (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

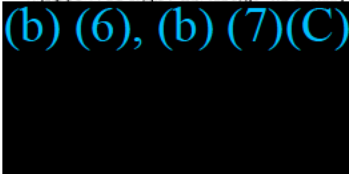
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-18XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-18XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-07n

1. USDA Reference Number

2. Application Reference Number 2003-18XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite.

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Brown County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

[CBI Deleted] -- *Codington County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 10 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 10 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-18XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 13, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-18XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-07n

1. USDA Reference Number

2. Application Reference Number 2003-18XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite.

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Brown County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

[CBI Deleted] -- *Codington County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-18XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 10 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 10 acres.

MONSANTO



CBI-DELETED

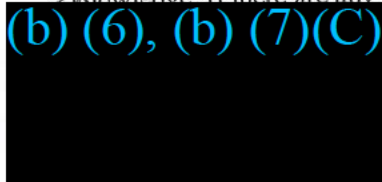
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-18XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



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OR120018_BR_009892



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2003

Dear Mr. Brown:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS- Protecting American Agriculture

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OR120018_BR_009893

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009894

file copy

January 17, 2003

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

Dear Mr. Brown:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009895

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:


Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009896

January 17, 2003

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).


Bp number 03-015-07n
Received: January 15, 2003
Institution: Monsanto
Interstate destination: KS MO MT SD
Release destination: SD

Applicant #: 2003-18XRAB
Effective: February 14, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

____ State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-07n	Applicant #:	2003-18XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 1/24/03

State: Montana

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_009898

JAN 24 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1238

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182



January 17, 2003

Dear Mr. Fridley:

Enclosed is notification 03-015-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-07n
Received: January 15, 2003
Institution: Monsanto
Interstate destination: KS MO MT SD
Release destination: SD

Applicant #: 2003-18XRAB
Effective: February 14, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stroaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Kevin Fridley

Signature:

(b) (6), (b) (7)(C)

Date:

1/24/03

State:

South Dakota

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

JAN 24 2003

OR120018_BR_009899

February 6, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2003.


Interstate movement and Release
Notification no. 03-015-07n (2003-18XRAB)
Regulated article - Wheat
Destinations - Kansas, Missouri, Montana, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 03-015-07n

OR120018_BR_009900

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-015-07n **Monsanto #2003-18XRAB**

March 2, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

(b) (4)

OR120018_BR_009901

(b) (4)

Codington County/SD (2147303325)

(b) (4)

OR120018_BR_009902

(b) (4)

OR120018_BR_009903

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-015-07n **Monsanto #2003-18XRAB**

March 2, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

Planting Date: 04/23/2003

Harvest Date: 08/07/2003

Destruct Date: 09/13/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Codington County/SD (2147303325)

Planting Date: 04/23/2003

Harvest Date: 08/12/2003

Destruct Date: 08/13/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

AHPIS Notification Number: 03-015-070

Applicant's Name: (b) (6), (b) (7)(C)

Name of Cooperator at inspection site: (b) (6), (b) (7)(C), (b) (4)

Location of site: (b) (6), (b) (7)(C), (b) (4)

Type of location: Farm ☒ Nursery ☐ Other ☐ (describe) Spink Co.

GPS/ GIS Coordinates (if available): Latitude _____

Crop: wheat

Trait/Gene: HT

Phone: (b) (6), (b) (7)(C), (b) (4)

Date of Inspection: 7-15-03

Longitude _____

Provide the answers below. Check "Y" for Yes and "N" for No. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting & harvest site, borders, field cages, etc.)? Y ☒ N ☐
- B. Was a site map obtained or drawn by your for reference later (For harvest, flower removal, volunteers, etc.)? Y ☒ N ☐

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? no plantings within miles Y ☒ N ☐
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants? Y ☒ N ☐
- C. Which of the five containment options is the applicant using? Check one of the options below. If none, please note it here and state this in your cover letter to the Regional Program Manager. _____

1. Removing Flowers _____
Is there any evidence that the plants have flowers or that flowers have been removed? Y ☐ N ☐

2. Bagging Flowers/Tassels _____
Does the applicant have material to bag reproductive structures? Y ☐ N ☐

3. Terminating the experiment before flowering _____
Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y ☐ N ☐

4. Physical Isolation ☒
If there are any non-transgenic compatible plants within the distance stated in Table 1 (for pollination distance), were they being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? no plantings of cultivated crop within miles Y ☐ N ☐

5. Temporal Isolation _____
Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y ☐ N ☐

D. If the applicant's design standards use border rows, are there the stated number of border rows? Y ☒ N ☐
no rows needed

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Y ☒ N ☐
no other plantings within miles

Revised 7/2/03

OR120018_BR_009908

- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? *volunteers removed 5/28, 5/30, 6/5, 6/24, and last week* Y ☒ N ☐
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y ☒ N ☐
- H. Was the field site marked as stated in the design standards? Y ☒ N ☐
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y ☒ N ☐
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? *equipment cleaned on site site disked* Y ☒ N ☐

III. Devitalization

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y ☒ N ☐
- B. Remind applicant that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed and approved.

(b) (6), (b) (7)(C), (b) (4)

Inspecting Officer Signature

Printed Name: Amy Mesman

Phone: 605/224-1713

Location of PPQ Officer: Pierre SD

Names and Affiliation of Any Other Persons at the inspection:

Please fax or email completed worksheet to:

Ralph Stoaks, Regional Biotechnologist

2150 Centre Ave. Bldg. B, 3E10

Ft. Collins, CO 80526

Phone: 970-494-7573

Fax: 970-494-7576

Email: ralph.d.stoaks@aphis.usda.gov

planted 4-23-03

harvest first of August

received 2 containers of 120 and 70 pounds

Please FedEx original worksheet to:

Tony Roman, Chief Biotechnology Program Operations

4700 River Road, Unit 147, 5B53

Riverdale, MD 20737

Phone: 301-734-0029

(b) (4)

1/17/03 12:20 pm

Notification Tracking Sheet

=====
Bp number: 03-015-08n
=====

App number: 2003-19XRAB
Received: 1/15/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/12/03
End movement: 2/12/04
Begin release: 2/12/03
End release: 2/12/04
Acre: 15.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [1/22/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>JMC</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLN</i>] | [1/23/03]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*ID	*	*WR	*	[]
Interstate	*Dest*KS	*	*SCR	*	[]
Interstate	*Dest*MO	*	*SCR	*	[]
Interstate	*Dest*MT	*	*WR	*	[]
Interstate	*Dest*WA	*	*WR	*	[]
Interstate	*Orig*ID	*	*WR	*	
Interstate	*Orig*KS	*	*SCR	*	
Interstate	*Orig*MO	*	*SCR	*	
Interstate	*Orig*MT	*	*WR	*	
Interstate	*Orig*WA	*	*WR	*	
Release	*WA	*	3*WR	*	[]

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLN</i>] | [1/28/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLN</i>] | [1/29/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

OR120018_BR_009911

**CONFIDENTIAL**

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>**Monsanto Reference ID**
2003-19XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-08n

1. USDA Reference Number**2. Application Reference Number** 2003-19XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite

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designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this permit Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

* (b) (4) Latah County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

]CBI

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

]CBI

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

]CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2003-19XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA,

J-CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

WA

* (b) (4) Adams County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

J-CBI

* (b) (4) Benton County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

J-CBI

* (b) (4) Whitman County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

* (b) (4) Walla Walla County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Whitman

CONFIDENTIAL

Monsanto Reference ID
2003-19XRAB

County/Province, WA (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-19XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

[(b) (4) Adams County/Province, WA, (b) (4) USA, 5
acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Whitman County/Province, WA, (b) (4)
USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Walla Walla County/Province,
WA (b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

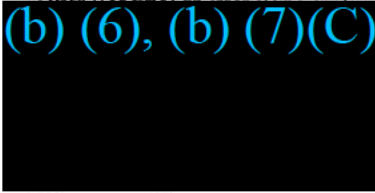
*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>**Monsanto Reference ID**
2003-19XRAB**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C. Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

Monsanto Reference ID
2003-19XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-08n

1. USDA Reference Number

2. Application Reference Number 2003-19XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-19XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-19XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this permit Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2003-19XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres.

[CBI Deleted] -- Whitman County/Province, WA, USA, 5 acres.

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

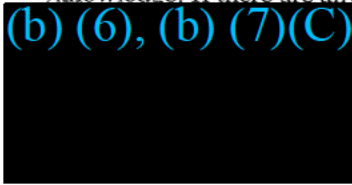
<http://www.monsanto.com>

Monsanto Reference ID
2003-19XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-19XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-08n

1. USDA Reference Number

2. Application Reference Number 2003-19XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID

2003-19XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

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CBI-DELETED

Monsanto Reference ID

2003-19XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
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A total of 3000 pounds of seed may be shipped for the duration of this permit Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2003-19XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres.

[CBI Deleted] -- Whitman County/Province, WA, USA, 5 acres.

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-19XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 13, 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009932



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2003

Dear Mr. Brown:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



file copy

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2003

Dear Mr. Cooper:


Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
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Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009934

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009935

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2003

Dear Mr. Brown:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009936

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009937

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 17, 2003

Dear Mr. Wessels:


Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

____ State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2003

RECEIVED

JAN 24 2003

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 03-015-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-08n	Applicant #:	2003-19XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael F. Cooper

Signature: (b) (6), (b) (7)(C)

Date: 1/27/03

State: Idaho

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date:

1/24/03

State:

Montana

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009940

JAN 24 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 17, 2003

Dear Mr. Wessels:

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Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: ID KS MO MT WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/27/03

State: _____

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

JAN 27 2003

OR120018_BR_009941

January 28, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2003.

Interstate movement and Release
Notification no. 03-015-08n (2003-19XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Cooper, Idaho State Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 03-015-08n

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-015-08n **Monsanto #2003-19XRAB**

January 30, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147306778	Adams	WA	Not Planted
2147306763	Whitman	WA	Not Planted
2147312318	Walla Walla	WA	

Walla Walla County/WA (2147312318)

(b) (4)

2/2/04
apl

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-015-08n Monsanto #2003-19XRAB

January 30, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147306778	Adams	WA	Not Planted
2147306763	Whitman	WA	Not Planted
2147312318	Walla Walla	WA	

Walla Walla County/WA (2147312318)

Planting Date: 03/31/2003

Harvest Date: 07/16/2003

Destruct Date: 07/28/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/15/2003

Harvest Date: 07/25/2003

Destruct Date: 07/28/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-015-08n **Monsanto #2003-19XRAB**

January 30, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147306778	Adams	WA	Not Planted
2147306763	Whitman	WA	Not Planted
2147312318	Walla Walla	WA	

Walla Walla County/WA (2147312318)

(b) (4)

2/2/04
apl

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

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* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

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Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

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NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

7/30/03

APHIS Notification Number(s): 03-015-08n Crop: Wheat (Hard red spring)
Applicant's Name: Monsanto Trait/Gene: (b) (4), (b) (6), (b) (7)(C)
Name of Cooperator at Inspected Site: (b) (4), (b) (6), (b) (7)(C) Phone: (b) (4), (b) (6), (b) (7)(C)
Location of Site: (b) (4), (b) (6), (b) (7)(C) Date of Inspection: 7/14/03
Type of Location: Farm ☐ Nursery ☐ Research ☒ Other ☐ (Describe) (b) (4), (b) (6), (b) (7)(C)
GPS Coordinates (If available): Latitude (b) (4), (b) (6), (b) (7)(C) Longitude (b) (4), (b) (6), (b) (7)(C)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Y ☒ N ☐
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Y ☒ N ☐

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y ☒ N ☐
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? Y ☒ N ☐
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- _____ 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y ☐ N ☐
- _____ 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? Y ☐ N ☐
- _____ 3. Terminating the experiment before flowering.
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y ☐ N ☐
- ☒ 4. Physical isolation.
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? Y ☒ N ☐
- _____ 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y ☐ N ☐

Procedure

- D. If the applicant's design standards use border rows, are there the state number of border rows? Y N
- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Y N
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y N
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y N
- H. Was the field site marked as stated in the design standards? Y N
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y N
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y N

III. Devitalization.

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y N
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: George Bruno Phone: (509) 353-2950

Location of PPQ Office Spokane, WA

Names and Affiliation of Any Other Persons at the Inspection:

Sheldon Blank - Cooperator

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.

(b) (6), (b) (7)(C)

Domestic Programs Coordinator

Ralph D Stoaks
Sent by: Ralph D Stoaks

07/29/2003 09:53

To: George A Bruno/WA/APHIS/USDA@USDA
cc: Kristen M House/CO/APHIS/USDA@USDA, Steven M
Miller/WA/APHIS/USDA@USDA, Juan A
Roman/MD/APHIS/USDA@USDA
Subject: Biotech inspection report 03-015-08N

George, Thank you for the good report and for taking time to send it with original signature to Tony Roman. We look forward to your future reports.

Kristen, Please record attached report to Access.

Ralph

----- Forwarded by Ralph D Stoaks/CO/APHIS/USDA on 07/29/2003 07:47 AM -----

George A Bruno
07/28/2003 06:59 PM

To: Ralph D Stoaks/CO/APHIS/USDA@USDA
cc: Steven M Miller/WA/APHIS/USDA@USDA
Subject: Biotech inspection report

Dr. Ralph Stoaks, Regional Biotechnologist

Permit No. 03-015-08n

(b) (4), (b) (6), (b) (7)(C)

George Bruno
Domestic Programs Coordinator

OR120018_BR_009955

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

6/20/03

PERMIT NUMBER 03-015-08N CROP Wheat (Hard red spring)

ORGANIZATION /COMPANY Monsanto

LOCATION

(b) (4)

WA

DATE OF PPQ NOTIFIED OF HARVEST 7/14/03 ACTUAL HARVEST DATE 7/16, 7/25

DATE OF HARVEST INSPECTION 8/7/03

HOW WAS CROP TERMINATED? Harvested with Combine (Hege 140) and Plowed under.

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Plant debris and stubble worked into soil using a harrow.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? High pressure air on site. Shop vac used to remove all plant debris from access.

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? yes WHEF

(b) (4)

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes (listed on application as destination for shipment of transgenic material)

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes, Monitor 2 years for volunteers

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

George Bruno
INSPECTING PPQ OFFICER George Bruno

PHONE (509) 353-2950

LOCATION OF PPQ OFFICE SPOKANE, WA

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

REVISED 01/24/97

OR120018_BR_009956

1/17/03 12:20 pm

Notification Tracking Sheet

=====
Bp number: 03-015-09n
=====

App number: 2003-21XR
Received: 1/15/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement:
End movement:
Begin release: 2/12/03
End release: 2/12/04
Acre: 30.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [1/22/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>JMC</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLn</i>] | [1/23/03]* |
| 4. <input type="checkbox"/> State response | | |

- | | O/d | Loc | Site | Reg | | |
|---------|-----|-----|------|-------|---|-----|
| Release | * | *CO | * | 1*WR | * | [] |
| Release | * | *NE | * | 1*SCR | * | [] |
| Release | * | *WY | * | 1*WR | * | [] |
-
- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLn</i>] | [1/29/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLn</i>] | [1/31/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

*CONFIDENTIAL*

Monsanto Reference ID
2003-21XR

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-09n

1. USDA Reference Number

2. Application Reference Number 2003-21XR

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Release February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

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Monsanto Reference ID
2003-21XR

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-21XR

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Release

Ship up to _____ pounds wheat seed to and from each location.

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Monsanto Reference ID
2003-21XR

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1), NE(1), WY(1)

CO

(b) (4) Larimer County/Province, CO, (b) (4)
U.S.A., 10 acres. (979)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

NE

(b) (4) Scotts Bluff
County/Province, NE, (b) (4) U.S.A., 10 acres. (591)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) NE, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

J-CBI

WY

(b) (4) Goshen County/Province, WY (b) (4)
U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WY, (b) (4), (b) (6), (b) (7)(C) United States of America (b) (4), (b) (6), (b) (7)(C)

J-CBI

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2003-21XR

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 13, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir. 1979).

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Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

Monsanto Reference ID
2003-21XR

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-09n

1. USDA Reference Number

2. Application Reference Number 2003-21XR

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Release February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-21XR

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-21XR

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Release

Ship up to _____pounds wheat seed to and from each location.

CBI-DELETED

Monsanto Reference ID
2003-21XR

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1), NE(1), WY(1)

CO

[CBI Deleted] -- Larimer County/Province, CO, U.S.A, 10 acres.

NE

[CBI Deleted] -- Scotts Bluff County/Province, NE, U.S.A., 10 acres.

WY

[CBI Deleted] -- Goshen County/Province, WY, U.S.A., 10 acres.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

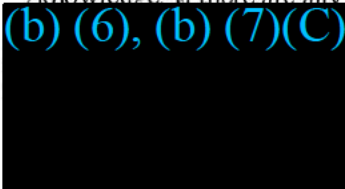
CBI-DELETED

Monsanto Reference ID
2003-21XR

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-21XR

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-09n

1. USDA Reference Number

2. Application Reference Number 2003-21XR

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Release February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-21XR

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

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CBI

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CBI-DELETED

Monsanto Reference ID
2003-21XR

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PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Release

Ship up to _____ pounds wheat seed to and from each location.

CBI-DELETED

Monsanto Reference ID
2003-21XR

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1), NE(1), WY(1)

CO

[CBI Deleted] -- Larimer County/Province, CO, U.S.A, 10 acres.

NE

[CBI Deleted] -- Scotts Bluff County/Province, NE, U.S.A., 10 acres.

WY

[CBI Deleted] -- Goshen County/Province, WY, U.S.A., 10 acres.

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID
2003-21XR

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 13, 2003

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 17, 2003

Dear Mr. Yergert:

Enclosed is notification 03-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-09n	Applicant #:	2003-21XR
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO NE WY		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009976



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
5940 S. 58th Street
Lincoln, NE 68516

January 17, 2003

Dear Mr. Johnson:

Enclosed is notification 03-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-09n	Applicant #:	2003-21XR
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO NE WY		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



file copy

Mr. Henry R. Uhden, Agriculture Plant Industry Manager
Consumer and Compliance Division
Wyoming Department of Agriculture
2219 Carey Avenue
Cheyenne, WY 82002

January 17, 2003

Dear Mr. Uhden:

Enclosed is notification 03-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-09n	Applicant #:	2003-21XR
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO NE WY		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009978



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Mitch Vergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894



January 17, 2003

Dear Mr. Vergert:

Enclosed is notification 03-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-09n	Applicant #:	2003-21XR
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO NE WY		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL VERGERT

Signature: (b) (6), (b) (7)(C)

Date: JANUARY 28, 2003

State: COLORADO

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009979

JAN 28 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Henry R. Uhden, Agriculture Plant Industry Manager
Consumer and Compliance Division
Wyoming Department of Agriculture
2219 Carey Avenue
Cheyenne, WY 82002

January 17, 2003

Dear Mr. Uhden:

Enclosed is notification 03-015-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-09n Applicant #: 2003-21XR
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination:
Release destination: CO NE WY

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State Official: _____

Signature: _____

Date: 1/24/03

State: Wyoming

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009980

TOTAL P.01

JAN 24 2003

January 29, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2003.

Release

Notification no. 03-015-09n (2003-21XR)

Regulated article - Wheat

Destinations - Colorado, Nebraska, Wyoming

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE
H. Uhden, Wyoming Dept. of Agric., Cheyenne, WY
File number 03-015-09n

OR120018_BR_009981

Confirmation Report-Memory Send

Time : Jan-29-03 02:37pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 205
Date : Jan-29 02:36pm
To : 916367377085
Document Pages : 02
Start time : Jan-29 02:36pm
End time : Jan-29 02:37pm
Pages sent : 02
Job number : 205

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

January 29, 2003

(b) (6), (b) (7)(C)

700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2003.

Release

Notification no. 03-015-09n (2003-21XR)

Regulated article - Wheat

Destinations - Colorado, Nebraska, Wyoming

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Vergert, Colorado Dept. of Agric., Lakewood, CO
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE
H. Uhden, Wyoming Dept. of Agric., Cheyenne, WY



APHIS-Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009982

No CBI

2003 Wheat Field Test Report
USDA #03-015-09n **Monsanto #2003-21XR**

February 17, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
979	Larimer	CO	Not Planted
591	Scotts Bluff	NE	Not Planted
2147303936	Goshen	WY	Not Planted

ajl
2/18/04

NOTICE

CONFIDENTIAL BUSINESS INFORMATION

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section (b) (4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

Identification Number:

03-015-10N

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

**Please disqualify yourself if there is
any potential Conflict of Interest**

NOTICE

CONFIDENTIAL BUSINESS INFORMATION

1/17/03 12:20 pm

Notification Tracking Sheet

=====
Bp number: 03-015-10n
=====

App number: 2003-22XRAB
Received: 1/15/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/12/03
End movement: 2/12/04
Begin release: 2/12/03
End release: 2/12/04
Acre: 100.00
CBI status: CBI
Fax: 636-737-7085
=====

- | | Initial | Date |
|--------------------------------------------------------------------------------------|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [1/22/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>JMC</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLn</i>] | [1/23/03]* |
| 4. [] State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*
Interstate	*Dest*	MN	*	*NER	*
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	MT	*	*WR	*
Interstate	*Dest*	ND	*	*SCR	*
Interstate	*Dest*	SD	*	*SCR	*
Interstate	*Orig*	KS	*	*SCR	*
Interstate	*Orig*	MN	*	*NER	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	MT	*	*WR	*
Interstate	*Orig*	ND	*	*SCR	*
Interstate	*Orig*	SD	*	*SCR	*
Release	*	ND	*	10*SCR	*

- | | | |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLn</i>] | [3/13/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLn</i>] | [3/14/03] |
| 8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-22XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-10n

1. USDA Reference Number

2. Application Reference Number 2003-22XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

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Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-22XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10000 pounds of seed may be shipped for the duration of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, MT, ND, SD

DESTINATION:

KS, MN, MO, MT, ND, SD

Ship From/Ship To:

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

J-CBI

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA

J-CBI

MN

* (b) (4), Ramsey County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA

J-CBI

MO

* (b) (4) St. Louis County/Province, MO,

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

(b) (4) USA

CONTACT:
(b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C)

MO,

] -CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT:
USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C)

] -CBI

ND

* (b) (4) Williams
County/Province, ND, (b) (4) USA

CONTACT:
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Mountrail County/Province, ND, (b) (4) USA

CONTACT:
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] -CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT:
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT:
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

* (b) (4) Burke County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Burke County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Foster County/Province,
ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Ward County/Province, ND,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cass County/Province,
ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cass County/Province, ND, (b) (4)
USA

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cavalier
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

* (b) (4) Brookings
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(10)

ND

(b) (4)
ND, (b) (4) USA, 10 acres. (b) (4) Williams County/Province,

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4), (b) (6), (b) (7)(C) Burke County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

CONFIDENTIAL

Monsanto Reference ID
2003-22XRAB

(b) (4) Foster County/Province, ND,
(b) (4) U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Ward County/Province, ND,
(b) (4) U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Cass County/Province, ND (b) (4) USA,
10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Cass County/Province, ND, (b) (4) USA,
10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Langdon, Cavalier
County/Province, ND, (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-22XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 13, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2003-22XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-10n

1. USDA Reference Number

2. Application Reference Number 2003-22XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/15	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10000 pounds of seed may be shipped for the duration of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, MT, ND, SD

DESTINATION:

KS, MN, MO, MT, ND, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cavalier County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(10)

ND

- [CBI Deleted] -- Williams County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Mountrail County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Burke County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres.
- [CBI Deleted] -- Ward County/Province, ND, U.S.A., 10 acres.
- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

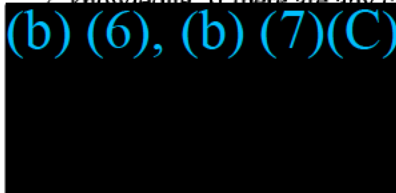
Monsanto Reference ID

2003-22XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-22XRAB

Permit Unit

January 13, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-015-10n

1. USDA Reference Number

2. Application Reference Number 2003-22XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 12, 2003 - February 12, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10000 pounds of seed may be shipped for the duration of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, MT, ND, SD

DESTINATION:

KS, MN, MO, MT, ND, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cavalier County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-22XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(10)

ND

- [CBI Deleted] -- Williams County/Province, ND, USA, 10 acres.
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- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
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- [CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.
- [CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres.

MONSANTO



CBI-DELETED

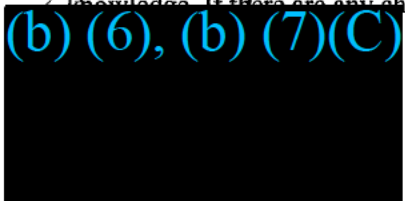
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-22XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 13, 2003

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010010

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 17, 2003

Dear Dr. Hanks:


Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010011

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2003

Dear Mr. Brown:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010012

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:


Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010013

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 17, 2003

Dear Mr. Nelson:


Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010014

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 17, 2003

Dear Mr. Fridley:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-015-10n	Applicant #:	2003-22XRAB
Received:	January 15, 2003	Effective:	February 14, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010015



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



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OR120018_BR_010016



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

faxed 1-28-03

January 17, 2003

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

Dear Dr. Hanks:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

Not a FOIA Deletion

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 1-28-03

State: MN

Rptloc01/R4



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OR120018_BR_010017

JAN 28 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2003

Dear Mr. Brown:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 17, 2003

Dear Mr. Ames:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c):

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lorin H. Ham

Signature: (b) (6), (b) (7)(C)

Date: 1/24/03

State: Montana

Rptloc01/R4



APHIS-Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010019

JAN 24 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 17, 2003

Dear Mr. Nelson:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *in Supplemental Conditions letter March 12, 2003*
____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3/12/03

State: ND

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_010020

MAR 12 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 17, 2003



Dear Mr. Fridley:

Enclosed is notification 03-015-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-015-10n Applicant #: 2003-22XRAB
Received: January 15, 2003 Effective: February 14, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Steaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Kevin Fridley

Signature:

(b) (6), (b) (7)(C)

Date:

1/24/03

State:

South Dakota

Rpt10c01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

JAN 24 2003

OR120018_BR_010021

March 13, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 13, 2003.

Interstate movement and Release

Notification no. 03-015-10n (2003-22XRAB)

Regulated article - Wheat

Destinations - Kansas, Minnesota, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination for movement only.

In addition, the State of North Dakota has (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 03-015-10n

OR120018_BR_010022

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson

DATE: March 12, 2003

RE: Supplemental Conditions for Release of Wheat
Bp 03-015-10n
Bp 03-052-27n
Bp 03-052-59n
Bp 03-059-05n

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2003

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

OR120018_BR_010023

Confirmation Report-Memory Send

Time : Mar-14-03 01:11pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 830
Date : Mar-14 01:10pm
To : 916367377085
Document Pages : 03
Start time : Mar-14 01:10pm
End time : Mar-14 01:11pm
Pages sent : 03
Job number : 830

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 13, 2003

(b) (6), (b) (7)(C)

Interstate Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 13, 2003.

Interstate movement and Release
Notification no. 03-015-10n (2003-22KRAB)
Regulated article - Wheat

Destinations - Kansas, Minnesota, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination for movement only.

In addition, the State of North Dakota has (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
C. Ames, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



APHIS- Protecting American Agriculture

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OR120018_BR_010024

(b) (6), (b) (7)(C), (b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP wheat

ORGANIZATION / COMPANY Monwanto

RESPONSIBLE APPLICANT (b) (6), (b) (7)(C), (b) (4)

COOPERATOR CONTACT PERSON " "

LOCATION (b) (6), (b) (7)(C), (b) (4) PHONE (b) (6), (b) (7)(C), (b) (4)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other Montreal County N.D.

DATE PPQ NOTIFIED OF FIELD RELEASE 3/13/03 ACTUAL DATE OF

RELEASE 03/13/03

DATE OF FIELD INSPECTION 03/29/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER N/A
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? 600' x 210' YES ☐ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH field
SOUTH grass Pasture
EAST Road
WEST Grass

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED

NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left over

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor, cleaned in Plot Area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-3366

LOCATION OF PPQ OFFICE

OTHER PERSONS AT INSPECTION (b) (6), (b) (7)(C), (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010025

(b) (6), (b) (7)(C), (b) (4)



(b) (6), (b) (7)(C), (b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

aw
5/29/03

PERMIT NUMBER 03-015-10N CROP wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (6), (b) (7)(C), (b) (4)

COOPERATOR CONTACT PERSON (b) (6), (b) (7)(C), (b) (4)

LOCATION (b) (6), (b) (7)(C), (b) (4) PHONE (b) (6), (b) (7)(C), (b) (4)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☒ Research ☐ General ☐ Other

DATE PPQ NOTIFIED OF FIELD RELEASE 5/29/03 ACTUAL DATE OF
RELEASE 5/29/03

DATE OF FIELD INSPECTION 5/29/03

SITE INFORMATION: will find out when I travel to NDSU.

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? NA YES ☐ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH fallow
SOUTH grass pasture
EAST road
WEST grass

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☐ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED
NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Any left buried in Plot Area

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL?

Air Compressor, and cleaned in the Plot Area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE (b) (6), (b) (7)(C), (b) (4)

OTHER PERSONS AT INSPECTION

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ PHONE: 573-893-6833

OR120018_BR_010027

2

(b) (6), (b) (7)(C), (b) (4)



From

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (6), (b) (7)(C), (b) (4)

LOCATION (b) (6), (b) (7)(C), (b) (4) PHONE (b) (6), (b) (7)(C), (b) (4)

TYPE OF LOCATION: Farm Nursery ✓ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF 5/12/03 - Plot
RELEASE 5/21/03 - Weed Control

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ✓ NO
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? Flax YES NO ✓
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER None
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ✓ NO
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ✓ NO
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ✓ NO
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH Barley

SOUTH " "

EAST Canola

WEST Barley

8. BORDER BUFFER AREA REQUIRED? 330' YES ✓ NO

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ✓ NO

10. WAS SEED STORAGE AREA INSPECTED? yes - locked cabinet YES ✓ NO

11. WERE SHIPPING CONTAINERS INSPECTED? yes - Shipping Boxes were YES ✓ NO

in the cabinet LABELLED? YES ✓ NO

12. NUMBER OF REGULATED ARTICLES RELEASED 1.25 Acres

NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left -

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned on spot

INSPECTING PPQ OFFICER Wendell J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE W. Cushing

OTHER PERSONS AT INSPECTION (b) (6), (b) (7)(C), (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ PHONE: 573-893-6833

OR120018_BR_010029

(b) (6), (b) (7)(C), (b) (4)



NDSU

North Dakota State University
Research Extension Center
Box 310, Hwy. 5 East
Langdon, North Dakota
58249

Tel. 701.256.2582
Fax 701.256.2580
explang@ndsuxext.nodak.edu

FAX TRANSMISSION INFORMATION

Date: 6/20/03Number of pages including cover sheet 2

Please deliver the following page(s) to:

Name Wendal Cushing / Dale Williams ^{APIS} ^{Seed stocks} / Randy Mehlhoff

Address

From (b) (6), (b) (7)(C), (b) (4)

Comments:

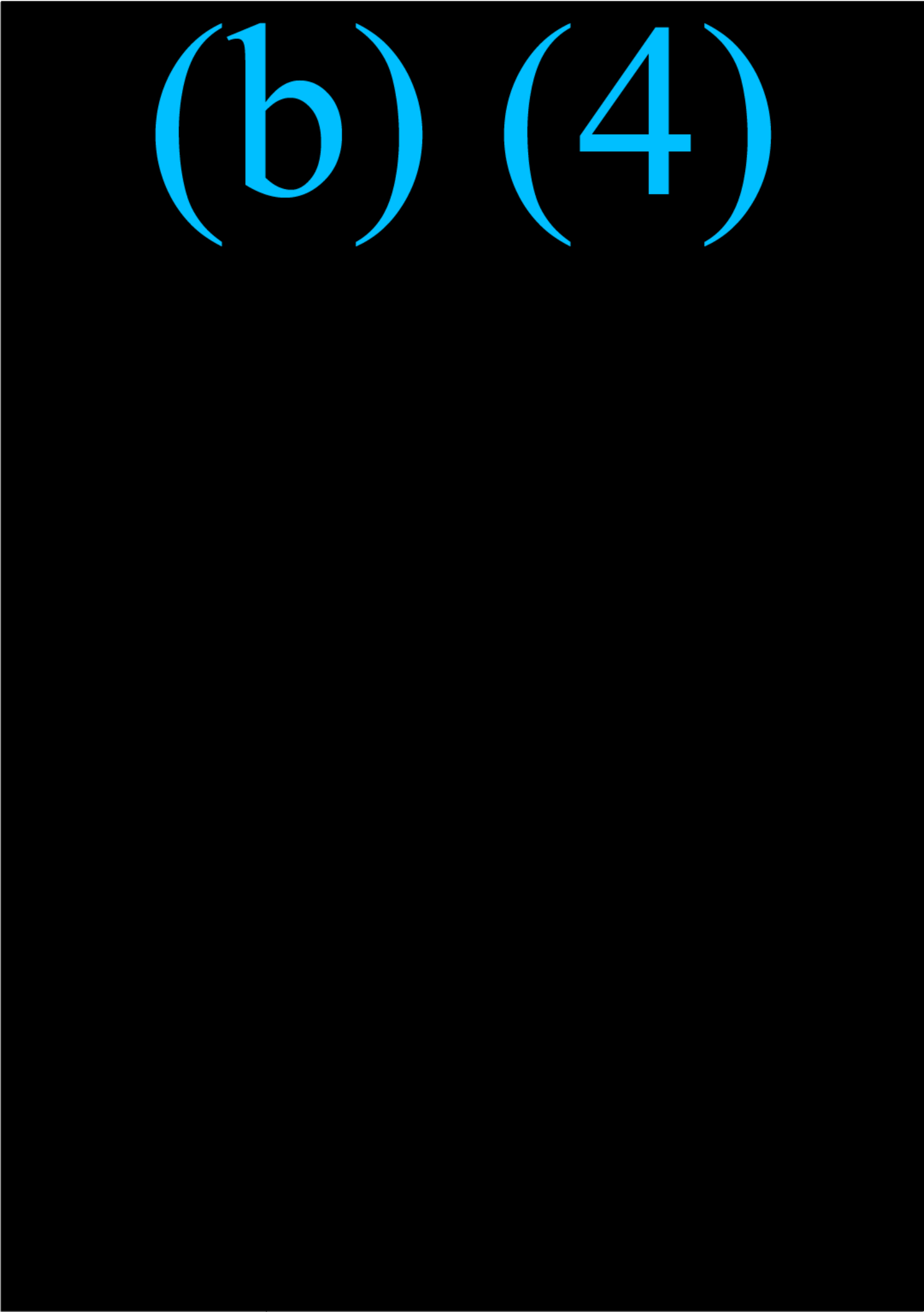
(b) (6), (b) (7)(C), (b) (4)

If you do not receive all of the pages, please call 701-256-2582

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(b) (4)



(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE 5/16/03 ACTUAL DATE OF
RELEASE 6/6/03 6-6-03

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES NO ☒ Blade worked 6/6/03
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER None
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH Tree line

SOUTH Soil heave

EAST Flax

WEST Road

8. BORDER BUFFER AREA REQUIRED? about 100' YES ☒ NO

330' from other wheat

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO

LABELLED? YES ☒ NO

12. NUMBER OF REGULATED ARTICLES RELEASED about 3 Acres

NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS 25# buried in field

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned in field - Drill still

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE

OTHER PERSONS AT INSPECTION only PPQ

Steve will harvest

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010033

(b) (4)

(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

6/18/03

PERMIT NUMBER 03-015-10A CROP Wheat Pature #10-11

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE 5/11/03 ACTUAL DATE OF
RELEASE 6/6/03

DATE OF FIELD INSPECTION 6/16/03
same site as 2 yrs ago -

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH fallow
SOUTH fallow then southern
EAST grass pasture in
WEST broodleaf crops

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐
330' from other wheat HOW MUCH? 35 ft. minimum
9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☐ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☐ NO ☐

LABELLED? YES ☐ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED 100+
NUMBER OF TRANSGENIC LINES IN TEST 1 (33391)

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS saved for seeding other permitted site

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? seeding equipment
cleaned inside border area and seed buried within plot area

INSPECTING PPQ OFFICER Wendel J. Cushing PHONE (701) 228-3825
LOCATION OF PPQ OFFICE Bothreau, N.D.

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ PHONE: 573-893-6833

OR120018_BR_010035

(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)

COOPERATOR CONTACT PERSON Steve Valenti

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF RELEASE _____

DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐

2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒

3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____

✓ 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐

✓ 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐

Fallow ✓ 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐

7. WHAT WAS ON EACH SIDE OF THE PLOT?

✓ NORTH Truss Beans

✓ SOUTH Beans

✓ EAST Soybeans

✓ WEST Soybeans

✓ 8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

✓ 12. NUMBER OF REGULATED ARTICLES RELEASED 1
NUMBER OF TRANSGENIC LINES IN TEST 1

✓ 13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Buried in Plot

✓ 14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? IN Plot
Air Compressor cleaned in Plot

INSPECTING PPQ OFFICER Wendel Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION No one else

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ PHONE: 573-893-6833

(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

C
8/18/03

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other

✓ DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF
RELEASE _____
DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

- ✓ 1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
- ✓ 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
- ✓ 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
- ✓ 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?
- ✓ NORTH Trees, Soybeans, ditch, road
- ✓ SOUTH Soybeans
- ✓ EAST Farm place
- ✓ WEST Soybeans
- ✓ 8. BORDER BUFFER AREA REQUIRED? 100 ft to any other wheat YES ☒ NO ☐ we have border that are
330 ft to wheat that may be saved for seed HOW MUCH? _____
9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐ closest wheat
10. WAS SEED STORAGE AREA INSPECTED? YES ☐ NO ☐ is approx.
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☐ NO ☐ 2000ft.

✓ 12. NUMBER OF REGULATED ARTICLES RELEASED 1
NUMBER OF TRANSGENIC LINES IN TEST _____

✓ 13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Buried in release site

✓ 14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? with a vacuum
in the research plot area

INSPECTING PPQ OFFICER Wendel J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10n CROP wheat

ORGANIZATION / COMPANY Monanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE 4/3/03 ACTUAL DATE OF
RELEASE June 6, 03

DATE OF FIELD INSPECTION June 17/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐

2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒

3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____

4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐

5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐

6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐

7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH oat

SOUTH corn, soybean

EAST soybean

WEST millet, oat, flax, sunflower, soybean

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

330' from other wheat.

HOW MUCH? 35 ft. minimum

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED 180*

NUMBER OF TRANSGENIC LINES IN TEST 1 (33391)

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS buried

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? seeding equipment
cleaned inside border and extra seed buried within plot area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-3366-

LOCATION OF PPQ OFFICE (b) (4), (b) (6), (b) (7)(C) 228-2825

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010042

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat
ORGANIZATION /COMPANY Monsanto (b) (4), (b) (6), (b) (7)(C)
LOCATION North Dakota
DATE OF PPQ NOTIFIED OF HARVEST 8/13/03 ACTUAL HARVEST DATE 8/20/03
DATE OF HARVEST INSPECTION 8/20/03
HOW WAS CROP TERMINATED? Harvested with a Hege #160 Harvester.
DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
All Plot debris was worked into the Plot Area -
Collected seed, was double bagged in the Plot Area and placed
in the original durable boxes, for shipment.
HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? by Vacuum and
air pressure -
WERE REGULATED ARTICLES SHIPPED OUT OF STATE? will be WHERE? to Halstead Kansas
PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes
DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes
DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendell J. Cushing PHONE (701) 228-2825
LOCATION OF PPQ OFFICE Bohmer, W. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEETPERMIT NUMBER 03-015-10N CROP wheatORGANIZATION/COMPANY Monsanto-

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

LOCATION North DakotaDATE OF PPQ NOTIFIED OF HARVEST 8/13/03 ACTUAL HARVEST DATE 8/20/03DATE OF HARVEST INSPECTION 8/20/03HOW WAS CROP TERMINATED? Harvested by a Hege Combine #160

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

All field (plot) debris will be worked into the soil in the plot area -HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? All harvest equipment was cleaned by vacuum and air pressureWERE REGULATED ARTICLES SHIPPED OUT OF STATE? N/A WHERE? N/APPQ PERMIT/CERTIFICATE TO SHIP FROM STATE N/ADOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yesDID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yesINSPECTING PPQ OFFICER Wendell G. Cochran PHONE (701) 228-2825LOCATION OF PPQ OFFICE Bellevue, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C) OR120018_BR_010048 (b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

Appendix 1.6

(b) (4), (b) (6), (b) (7)(C)

PERMIT NUMBER 03-015-10N

CROP wheat

ORGANIZATION/COMPANY H. Panto

(b) (4), (b) (6), (b) (7)(C)

LOCATION North Dakota

DATE OF PPQ NOTIFIED OF HARVEST 8/21/03 ACTUAL HARVEST DATE 8/22/03

DATE OF HARVEST INSPECTION 8/22/03

HOW WAS CROP TERMINATED? Harvested

DESCRIBE METHOD OF DISPOSAL OF REGULATED: (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Harvested - seed collected and placed in north Dakota State University locked foot locker like containers, and taken to The University for cleaning and testing

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL?

Harvester was cleaned in the plot area

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? No WHERE? No

✓ PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes

✓ DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendal J. Cushing

PHONE (701) 228-2825

LOCATION OF PPQ OFFICE Boothman, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMIN

8 This form

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)



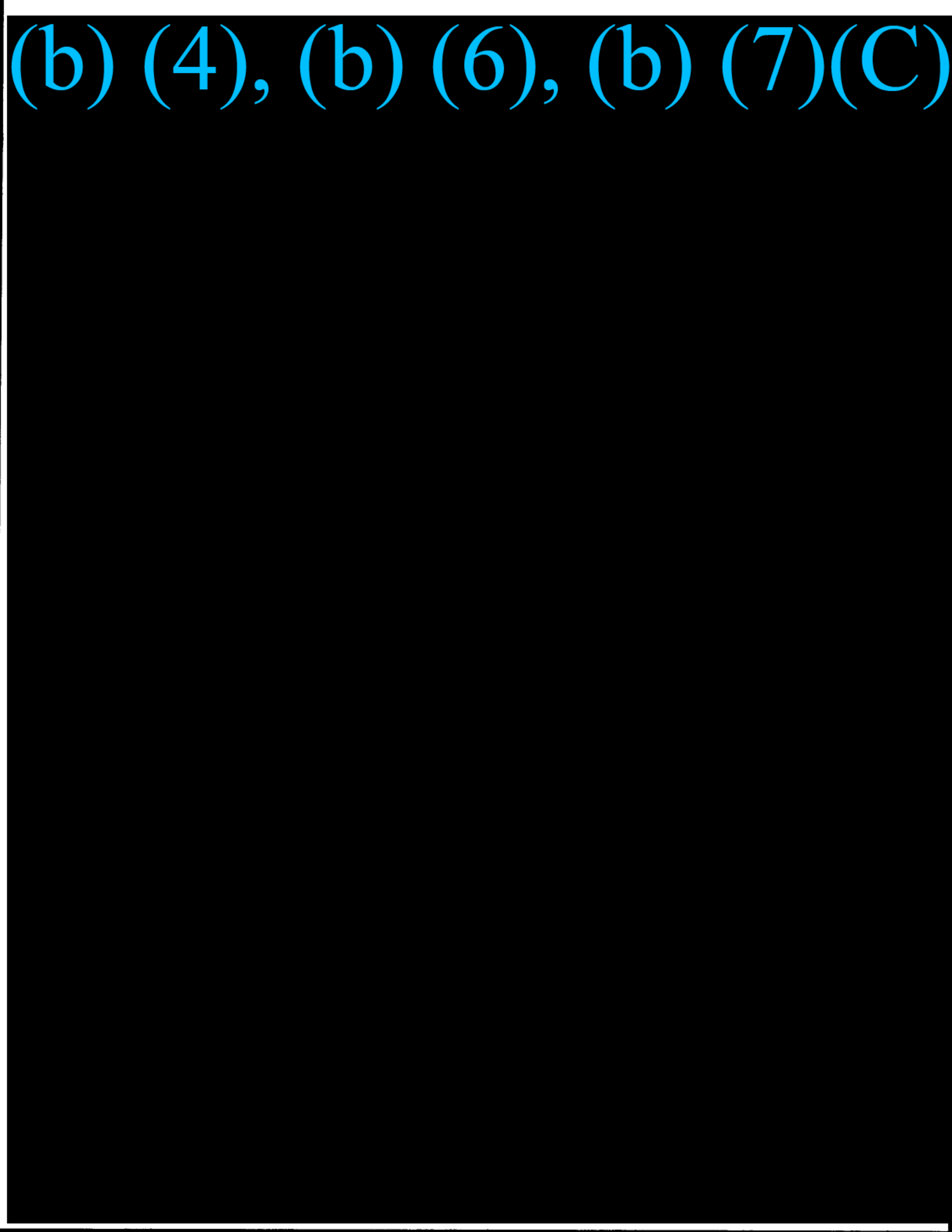
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)

OR120018_BR_010053



(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION /COMPANY Monsanto

(b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) North Dakota

DATE OF PPQ NOTIFIED OF HARVEST 9/5/03 ACTUAL HARVEST DATE 9/9/03

DATE OF HARVEST INSPECTION _____

HOW WAS CROP TERMINATED? Harvested

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Seed and harvest debris buried in the plot, then
cultivated into plot area

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Vacuum and
compressed air

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? N/A WHERE? _____

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE N/A

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendell J. Cushing PHONE (701) 225-2525

LOCATION OF PPQ OFFICE Bottineau, N. Dak.

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

PPQ officer, not able to be at harvest due to a work
related activity.

NDSU

LANGDON RESEARCH EXTENSION CENTER, AGRICULTURAL EXPERIMENT STATION

North Dakota State University
Research Extension Center
10, Hwy. 5 East
North Dakota
58249

Tel. 701.256.2582
Fax 701.256.2580
xplang@ndsuxst.nodak.edu

FAX TRANSMISSION INFORMATION

Date: 8/25/03Number of pages including cover sheet 1

Please deliver the following page(s) to:

Name Wendel CushmanAddress (b) (4), (b) (6), (b) (7)(C)From (b) (4), (b) (6), (b) (7)(C)

Comments:

We have it set up so all the
RR wheat at Langdon will be harvested
on Tuesday afternoon.

I am expecting both combines in here
shortly before dinner with probable start
right after dinner

(b) (4), (b) (6), (b) (7)(C)

If you do not receive all of the pages, please call 701-256-2582

NDSU is an equal opportunity institution

OR120018_BR_010056

(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat
 ORGANIZATION /COMPANY Monsanto (b) (4), (b) (6), (b) (7)(C)
 LOCATION (b) (4), (b) (6), (b) (7)(C) North Dakota
 DATE OF PPQ NOTIFIED OF HARVEST 8/25/03 ACTUAL HARVEST DATE 8/26/03
 DATE OF HARVEST INSPECTION 8/26/03
 HOW WAS CROP TERMINATED? Harvested - Combine
 DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
All plant material will be incorporated into the
soil, in the plot area
 HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air Compression and
Vacuum cleaners
 WERE REGULATED ARTICLES SHIPPED OUT OF STATE? yes WHERE? Halstead Kansas
 PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes
 DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes
 DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes
 INSPECTING PPQ OFFICER Wendal J. Custer PHONE (701) 228-2825
 LOCATION OF PPQ OFFICE Bohmian, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
 USDA, APHIS, PPQ
 9580 Micron Avenue, Suite 1
 Sacramento, CA 95827
 Phone: (916) 857-6105
 FAX: (916) 857-6100

Other People present at harvest
 1. John Zuckach
 2. Steve Valenti
 3. Doug Endorf - Minnesota Crop
 Improvement Assn

(b) (4), (b) (6), (b) (7)(C)

N.D.

(b) (4), (b) (6), (b) (7)(C)

Monsanto

Starting time of harvest 12:40

Harvest completed. 4:10

Cleaning of harvester - completed - 8:00 pm

Persons present at harvest.

Drill remains in The Plot Area

Bags - collected - mixed on site and 3 bags from each test
mixed and
were placed in one bag. All bags not used were burned
on site.

All collected material was double bagged and placed
in The Original Shipping containers for shipping -

Left Plot 8:00 pm

Wendel J. Cushing

Harvest Report Worksheet 2003

Date of Field Inspection	Planting Location	Crop	Permit Number	Responsible Person	Phone Number	GPS Reading
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N	(b) (4), (b) (6), (b) (7)(C)		
8/22/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-052-59N			
8/26/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
8/26/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-052-27N			
8/18/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
8/19/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
8/19/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
8/28/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-052-27N			
8/19/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Alfalfa	03-022-04N			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Sugar Beets	03-070-16N			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Sugar Beets	03-070-16N			
8/20/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			
8/20/03	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-015-10N			

Harvest Report Worksheet 2003

Date of Field Inspection	Planting Location	Crop	Permit Number	Responsible Person	Phone Number	GPS Reading
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-073-03N	(b) (4), (b) (6), (b) (7)(C)		
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-073-03N			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Wheat	03-073-03N			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Corn	03-022-01R			
	(b) (4), (b) (6), (b) (7)(C) N. Dak	Plot #1 Soybean	03-071-01R			
	(b) (4), (b) (6), (b) (7)(C) North Dakota	Plot #2 Soybean	03-071-01R			

Monitoring 2003 North Dakota Regulated Crop Harvest

Areas of concern: As indicated by the included photographs.

1. Compliance with the required protocol.
2. Movement of harvested material (seed) from the field
Or plot area, to a Laboratory, for examination.
3. Examination of harvested material, holding area,
shipping containers, and locked storage area.
4. Disposal of debris in the plot area, the working into
the soil or burying debris in a pit, or other means of
disposal.



RD 606219
602 Hwy 201 N
Carrington, ND 58401
Tel: 701-652-2951
fax: 701-652-2066

Fax

To: Wendal Cushing

From:

(b) (4), (b) (6), (b) (7)(C)

Fax: 701-228-2825

Pages: 1

Phone:

Date: 8/12/03

Re: RR wht harvest at Carrington

CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Wendal,
We are planning to harvest the Pounder Ready trials
at Carrington on Thursday, August 14 (± 10:30 a.m.
start).

(b) (4), (b) (6), (b) (7)(C)

* 8/13

Wendal,
We have a combine problem and will not harvest
tomorrow (Aug 14). I'll contact you ~~later~~ when we
are able to harvest - possibly Friday.

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEETPERMIT NUMBER 03-015-10N CROP wheatORGANIZATION /COMPANY MonsantoLOCATION (b) (4), (b) (6), (b) (7)(C) North DakotaDATE OF PPQ NOTIFIED OF HARVEST 8/13/03 ACTUAL HARVEST DATE 8/18/03DATE OF HARVEST INSPECTION 8/18/03HOW WAS CROP TERMINATED? Harvested

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Crop debris worked into the soil, all harvested seed was buried in a pit 3' deep and covered immediately after harvest.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? all equipment was cleaned by vacuum and air pressureWERE REGULATED ARTICLES SHIPPED OUT OF STATE? N/A WHERE? N/APPQ PERMIT/CERTIFICATE TO SHIP FROM STATE N/ADOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yesDID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yesall protocol was followedINSPECTING PPQ OFFICER Wendal J. Lushington PHONE (701) 228-2825LOCATION OF PPQ OFFICE Bohmian, N Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100Others present at harvest

1. (b) (4), (b) (6), (b) (7)(C)
2. (b) (4), (b) (6), (b) (7)(C)
3. (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)



Wendal Cushing

From: (b) (4), (b) (6), (b) (7)(C)@ndsuext.nodak.edu>

To: (b) (4), (b) (6), (b) (7)(C)

Sent: Wednesday, August 13, 2003 7:51 AM

Wendal,

I understand (b) (4), (b) (6), (b) (7)(C) has informed you that his RR wheat will be harvested on Thursday, August 14. Steve will be harvesting NW22, Fargo (one of the locations on USDA# 03-015-10n) Friday, August 15, as well as his location near (b) (4), (b) (6), (b) (7)(C). The (b) (4), (b) (6), (b) (7)(C) second location for USDA# 03-015-10n) is scheduled for harvest Monday, August 18. If you are here for harvesting NW22, do you need to come back for harvest at (b) (4), (b) (6), (b) (7)(C)

see you soon,

kh

(b) (4), (b) (6), (b) (7)(C)

NDSU - Department of Plant Sciences
470-F Loftsgard Hall
Fargo, ND 58105-5051

office (b) (4), (b) (6), (b) (7)(C)

fax (701) 231-8474

e-mail (b) (4), (b) (6), (b) (7)(C)@ndsuext.nodak.edu

8/13/2003

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(b) (4), (b) (6), (b) (7)(C)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEETPERMIT NUMBER 03-015-10N CROP WheatORGANIZATION /COMPANY Monsanto (b) (4), (b) (6), (b) (7)(C)LOCATION (b) (4), (b) (6), (b) (7)(C) N. DakDATE OF PPQ NOTIFIED OF HARVEST 8/13/03 ACTUAL HARVEST DATE 8/19/03DATE OF HARVEST INSPECTION 8/19/03HOW WAS CROP TERMINATED? Harvested with Combine

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Crop debris was reduced by using a flail chopper and
The remaining debris was worked into the soil, any
seed harvested was buried in the plot area.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Vacuum and
Air, CleaningWERE REGULATED ARTICLES SHIPPED OUT OF STATE? N/A WHERE? N/APPQ PERMIT/CERTIFICATE TO SHIP FROM STATE N/ADOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS?

Protocol was followed.INSPECTING PPQ OFFICER Wendell J. Cushing PHONE (701) 228-2825LOCATION OF PPQ OFFICE Bottineau, N Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager

USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

Persons at harvest

1. (b) (4), (b) (6), (b) (7)(C)
2. [REDACTED]
3. [REDACTED]

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

OR120018_BR_010069

(b) (4), (b) (6), (b) (7)(C)



Appendix 1.6

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat
ORGANIZATION/COMPANY Monsanto (b) (4), (b) (6), (b) (7)(C)
LOCATION North Dakota
DATE OF PPQ NOTIFIED OF HARVEST 8/13/03 ACTUAL HARVEST DATE 8/19/03
DATE OF HARVEST INSPECTION 8/19/03
HOW WAS CROP TERMINATED? Harvested
DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
Straw from harvest was placed in a 3' deep pit and covered with a Bob Cat loader. Other remaining plant debris was worked in to the soil in the plot area.
HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? _____
WERE REGULATED ARTICLES SHIPPED OUT OF STATE? N/A WHERE? N/A
PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE N/A
DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes
DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825
LOCATION OF PPQ OFFICE Bohannon, N. Dakota

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager Other at harvest
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

1. (b) (4), (b) (6), (b) (7)(C)
2. (b) (4), (b) (6), (b) (7)(C)
3. (b) (4), (b) (6), (b) (7)(C)
4. (b) (4), (b) (6), (b) (7)(C)

REVISED 01/24/97

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

The new name/address information is:

(b) (4)

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010072

MONSANTO



CBI - DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

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<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:
[CBI DELETED] - Cavalier, ND

The new name/address information is:
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010073

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

8/18/03

PERMIT NUMBER 03-015-10N CROP wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT Steve Valenti

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) U. Dale PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF
RELEASE _____

DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐

2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒

3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____

✓ 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐

✓ 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐

✓ 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐

7. WHAT WAS ON EACH SIDE OF THE PLOT?

✓ NORTH Tree Beans

✓ SOUTH Beans

✓ EAST Soybeans

✓ WEST Soybeans

✓ 8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

✓ 12. NUMBER OF REGULATED ARTICLES RELEASED 1

NUMBER OF TRANSGENIC LINES IN TEST 1

✓ 13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Buried / In Plot

✓ 14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? IN Plot

Air Compressor cleaned in Plot-

INSPECTING PPQ OFFICER Wendel X. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION No one else

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010074

(b) (4), (b) (6), (b) (7)(C)



V

Fargo

(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

C
5/18/03

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) Cass Co. N. Dak PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other

✓ DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF

RELEASE

DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

✓ 1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐

2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒

3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____

✓ 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐

✓ 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐

✓ 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐

7. WHAT WAS ON EACH SIDE OF THE PLOT?

✓ NORTH Trees, soybeans, ditch, road

✓ SOUTH soybeans

✓ EAST Farm place

✓ WEST soybeans

✓ 8. BORDER BUFFER AREA REQUIRED? 100 ft to any other wheat YES ☒ NO ☐ we have borders

330 ft to wheat that may be saved for seed HOW MUCH? that are

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐ closest wheat

10. WAS SEED STORAGE AREA INSPECTED? YES ☐ NO ☐ is approx.

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☐ NO ☐ 2000ft.

LABELLED? YES ☐ NO ☐

✓ 12. NUMBER OF REGULATED ARTICLES RELEASED 1

NUMBER OF TRANSGENIC LINES IN TEST _____

✓ 13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Buried in release site

✓ 14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? with a vacuum

in the research plot area

INSPECTING PPQ OFFICER Wendel J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

8/18/03

PERMIT NUMBER 03-615-10n CROP wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: _____ Farm _____ Nursery ☒ Research _____ General _____ Other _____

DATE PPQ NOTIFIED OF FIELD RELEASE 4/3/03 ACTUAL DATE OF
RELEASE June 6, 03

DATE OF FIELD INSPECTION June 17/03

SITE INFORMATION:

- | | |
|--------------------------------------------------------------|--------------------------------------------------|
| 1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? | YES <input checked="" type="checkbox"/> NO _____ |
| 2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? | YES _____ NO <input checked="" type="checkbox"/> |
| 3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____ | |
| 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? | YES <input checked="" type="checkbox"/> NO _____ |
| 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? | YES <input checked="" type="checkbox"/> NO _____ |
| 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? | YES <input checked="" type="checkbox"/> NO _____ |
| 7. WHAT WAS ON EACH SIDE OF THE PLOT? | |

NORTH oat

SOUTH corn, soybean

EAST soybean

WEST millet, oat, flax, sunflower, soybean

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO _____
330' from other wheat. HOW MUCH? 35 ft. minimum

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO _____

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO _____

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO _____

LABELLED? YES ☒ NO _____

12. NUMBER OF REGULATED ARTICLES RELEASED 180[#]

NUMBER OF TRANSGENIC LINES IN TEST 1 (33391)

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS buried

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? seeding equipment
cleaned inside border and extra seed buried within plot area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-3366-

LOCATION OF PPQ OFFICE _____ 228-2825

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010080

(b) (4), (b) (6), (b) (7)(C)



(b) (4), (b) (6), (b) (7)(C)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

EW
8/8/03

PERMIT NUMBER 03-015-10N CROP Wheat Puttee #10-11

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON _____

LOCATION (b) (4), (b) (6), (b) (7)(C) N. Dak PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: _____ Farm _____ Nursery ☒ Research _____ General _____ Other _____

DATE PPQ NOTIFIED OF FIELD RELEASE 5/11/03 ACTUAL DATE OF RELEASE 6/6/03

DATE OF FIELD INSPECTION 6/16/03

Same site as 2 yrs ago -

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO _____
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES _____ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO _____
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO _____
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO _____
7. WHAT WAS ON EACH SIDE OF THE PLOT?

- NORTH fallow
✓ SOUTH fallow then soybean
✓ EAST grass pasture in s
✓ WEST broadleaf crops

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO _____

330' from other wheat

HOW MUCH? 35 ft. minimum

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO _____

10. WAS SEED STORAGE AREA INSPECTED? YES _____ NO _____

11. WERE SHIPPING CONTAINERS INSPECTED? YES _____ NO _____

LABELLED? YES _____ NO _____

12. NUMBER OF REGULATED ARTICLES RELEASED 100+
NUMBER OF TRANSGENIC LINES IN TEST 1 (33391)

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS saved for seeding other permitted site

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? seeding equipment cleaned inside border area and seed buried within plot area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-3825
LOCATION OF PPQ OFFICE Bothreau, N.D.

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010082

(b) (4), (b) (6), (b) (7)(C)



from John →

(b) (4), (b) (6), (b) (7)(C)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) N.D. (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: _____ Farm _____ Nursery ☒ Research _____ General _____ Other _____

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF RELEASE 5/12/03 - Plot
5/21/03 - Weed Control

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO _____
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? Flax YES _____ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER None
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO _____
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO _____
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO _____
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH Barley

SOUTH " "

EAST Canola

WEST Barley

8. BORDER BUFFER AREA REQUIRED? 330' YES ☒ NO _____

HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO _____

10. WAS SEED STORAGE AREA INSPECTED? yes - locked cabinet YES ☒ NO _____

11. WERE SHIPPING CONTAINERS INSPECTED? yes - shipping boxes were in the cabinet YES ☒ NO _____

LABELLED? YES ☒ NO _____

12. NUMBER OF REGULATED ARTICLES RELEASED 1.25 Acres

NUMBER OF TRANSGENIC LINES IN TEST _____

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left -

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned on spot

INSPECTING PPQ OFFICER Wendel J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ PHONE: 573-893-6833

OR120018_BR_010084

(b) (4), (b) (6), (b) (7)(C)



NDSU

LANGDON RESEARCH EXTENSION CENTER, AGRICULTURAL EXPERIMENT STATION

North Dakota State University
Langdon Research Extension Center
Box 310, Hwy. 5 East
Langdon, North Dakota
58249

Tel. 701.256.2582
Fax 701.256.2580
explang@ndsuxext.nodak.edu

FAX TRANSMISSION INFORMATION

Date: 6/20/03Number of pages including cover sheet 2

Please deliver the following page(s) to:

Name Wendal Cushing / APIS

(b) (4), (b) (6), (b) (7)(C)

Address

From (b) (4), (b) (6), (b) (7)(C)

Comments:

Attached is map showing RRWht 01, 02, 03 at Langdon
and Gmo Barley⁰⁰ 01, 02, 03~~04~~ at Langdon

The closest seed wheat to 2003 RRWht is 450' and it is 550' to
the neighbors wht to the west.

The closest seed barley to 2003 Gmo Barley is 600' and the closest
barley of any kind is 330'.

All distances on map are rounded down.

(b) (4), (b) (6), (b) (7)(C)

If you do not receive all of the pages, please call (b) (4), (b) (6), (b) (7)(C)

NDSU is an equal opportunity institution.

OR120018_BR_010086

(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE 5/16/03 ACTUAL DATE OF

RELEASE 5/16/03 4-6-03

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒ *Black wheat 6/8/03*
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER None
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH Tree line

SOUTH Soil beans

EAST Flax

WEST Road

8. BORDER BUFFER AREA REQUIRED? about 100' YES ☒ NO ☐

330' from other wheat

HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐

10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED about 3 Acres

NUMBER OF TRANSGENIC LINES IN TEST _____

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS 25# buried in field

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? _____

Cleaned in field - Drill still

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION only PPQ

Have will harvest

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010088

(b) (4), (b) (6), (b) (7)(C)



CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

(b) (4), (b) (6), (b) (7)(C)

WC

2
5/29/03

PERMIT NUMBER 03-015-10N CROP wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: ☒ Farm ☐ Nursery ☒ Research ☐ General ☐ Other

DATE PPQ NOTIFIED OF FIELD RELEASE 5/29/03 ACTUAL DATE OF
RELEASE 5/29/03

DATE OF FIELD INSPECTION 5/29/03

SITE INFORMATION: will find out when I travel to NDSD.

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? NA YES ☐ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH field
SOUTH Grass Pasture
EAST Road
WEST Grass

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☐ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED

NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS Any left buried in Plot Area

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air Compressor, and cleaned in The Plot Area

INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE (b) (4), (b) (6), (b) (7)(C)

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010090

p

(b) (4), (b) (6), (b) (7)(C)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

(b) (4), (b) (6), (b) (7)(C)

PERMIT NUMBER 03-015-10N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)

COOPERATOR CONTACT PERSON " "

LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)

TYPE OF LOCATION: (b) (4), (b) (6), (b) (7)(C) montreal County N.D. (b) (4), (b) (6), (b) (7)(C)
☒ Farm ☐ Nursery ☐ Research ☐ General ☐ Other

DATE PPQ NOTIFIED OF FIELD RELEASE 3/13/03 ACTUAL DATE OF
RELEASE 03/13/03

DATE OF FIELD INSPECTION 03/29/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☒
3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER N/A
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? 600' x 210' YES ☐ NO ☐
7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH field
SOUTH Grass Pasture
EAST Road
WEST Grass

8. BORDER BUFFER AREA REQUIRED? YES ☒ NO ☐

HOW MUCH?

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO ☐
10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐
11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐

LABELLED? YES ☒ NO ☐

12. NUMBER OF REGULATED ARTICLES RELEASED

NUMBER OF TRANSGENIC LINES IN TEST

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left over

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor, cleaned in Plot Area

INSPECTING PPQ OFFICER Wendol J. Cushing PHONE (701) 228-3366

LOCATION OF PPQ OFFICE

OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010092

(b) (4), (b) (6), (b) (7)(C)



CONFIDENTIAL

2003 Wheat Field Test Report

USDA

Monsanto #2003-22XRAB

Not a FOIA Deletion

April 23, 2004

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
-896470389	Williams	ND	Not Planted
2147318001	Mountrail	ND	
2147307361	Cass	ND	
2147314745	Cass	ND	
2147307368	Burke	ND	Not Planted
1611677957	Foster	ND	
2147310478	Ward	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	
2147320702	Cavalier	ND	

Mountrail County/ND (2147318001)

(b) (4)

4/26/04 epj

(b) (4)

Cass County/ND (2147307361)

(b) (4)

(b) (4)

Cass County/ND (2147314745)

(b) (4)

Foster County/ND (1611677957)

(b) (4)

Cass County/ND (2147307378)

(b) (4)

(b) (4)

Cass County/ND (2147303287)

(b) (4)

(b) (4)

Cavalier County/ND (2147320702)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-015-10n Monsanto #2003-22XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
-896470389	Williams	ND	Not Planted
2147318001	Mountrail	ND	
2147307361	Cass	ND	
2147314745	Cass	ND	
2147307368	Burke	ND	Not Planted
1611677957	Foster	ND	
2147310478	Ward	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	
2147320702	Cavalier	ND	

Mountrail County/ND (2147318001)

Planting Date: 05/21/2003

Harvest Date: 09/09/2003

Destruct Date: 09/11/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147307361)

Planting Date: 05/16/2003

Harvest Date: 08/20/2003

Destruct Date: 08/21/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147314745)

Planting Date: 05/13/2003

Harvest Date: 08/20/2003

Destruct Date: 08/21/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Foster County/ND (1611677957)

Planting Date: 05/16/2003

Harvest Date: 08/18/2003

Destruct Date: 08/19/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147307378)

Planting Date: 04/28/2003

Harvest Date: 08/19/2003

Destruct Date: 08/19/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147303287)

Planting Date: 05/03/2003

Harvest Date: 08/19/2003

Destruct Date: 08/21/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cavalier County/ND (2147320702)

Planting Date: 05/12/2003

Harvest Date: 08/26/2003

Destruct Date: 08/27/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/22/03 10:27 am

Notification Tracking Sheet

=====
Bp number: 03-021-04n
=====

App number: 2003-20XRAB
Received: 1/21/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/20/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/15/03
End movement: 2/15/04
Begin release: 2/15/03
End release: 1/15/04
Acre: 20.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|--------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [1/22/03] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>V/M</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K&L</i>] | [1/23/03]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR	*
Interstate	*Dest*KS	*	*SCR	*
Interstate	*Dest*MO	*	*SCR	*
Interstate	*Dest*MT	*	*WR	*
Interstate	*Dest*WA	*	*WR	*
Interstate	*Orig*ID	*	*WR	*
Interstate	*Orig*KS	*	*SCR	*
Interstate	*Orig*MO	*	*SCR	*
Interstate	*Orig*MT	*	*WR	*
Interstate	*Orig*WA	*	*WR	*
Release	* *ID	*	4*WR	*

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K&L</i>] | [2/16/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K&L</i>] | [2/17/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-20XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-04n

1. USDA Reference Number**2. Application Reference Number** 2003-20XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant**Cultivar(s)/Variety(ies):** Lines derived from cultivar Bobwhite

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Monsanto Reference ID
2003-20XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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2003-20XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

* (b) (4) Bingham County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Bannock
County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, 83301,
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Latah County/Province,
ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

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Monsanto Reference ID
2003-20XRAB

] -CBI

* (b) (4) Latah County/Province, ID,
(b) (4)USAA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Latah County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA

] -CBI

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4)USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA

] -CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

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Monsanto Reference ID
2003-20XRAB

CONTACT (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

* (b) (4) Benton County/Province, WA (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

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Monsanto Reference ID
2003-20XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(4)

ID

(b) (4) Bingham County/Province, ID (b) (4) USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Bannock
County/Province, ID (b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Latah County/Province, ID,
(b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Latah County/Province, ID,
(b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-20XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 16, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-20XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-04n

1. USDA Reference Number

2. Application Reference Number 2003-20XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA
[CBI Deleted] -- *Bannock County/Province, ID, USA
[CBI Deleted] -- *Latah County/Province, ID, USA
[CBI Deleted] -- *Twin Falls County/Province, ID, USA
[CBI Deleted] -- *Latah County/Province, ID, USAA
[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA
[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(4)

ID

[CBI Deleted] -- Bingham County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Latah County/Province, ID, USAA, 5 acres.

MONSANTO



CBI-DELETED

Monsanto Reference ID
2003-20XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-20XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-04n

1. USDA Reference Number

2. Application Reference Number 2003-20XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA
[CBI Deleted] -- *Bannock County/Province, ID, USA
[CBI Deleted] -- *Latah County/Province, ID, USA
[CBI Deleted] -- *Twin Falls County/Province, ID, USA
[CBI Deleted] -- *Latah County/Province, ID, USAA
[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA
[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2003-20XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(4)

ID

[CBI Deleted] -- Bingham County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres.

[CBI Deleted] -- Latah County/Province, ID, USAA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

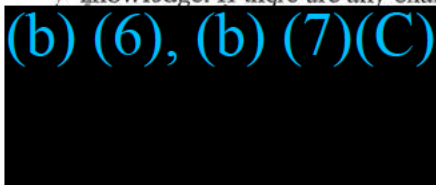
<http://www.monsanto.com>

Monsanto Reference ID
2003-20XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

file copy

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 22, 2003

Dear Mr. Cooper:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010129

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 22, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010130

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2003

Dear Mr. Brown:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010131

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 22, 2003

Dear Mr. Ames:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010132

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2003

Dear Mr. Wessels:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010133



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 22, 2003

RECEIVED

JAN 24 2003

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Cooper

Signature: (b) (6), (b) (7)(C)

Date: 1/27/03

State: Idaho

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 22, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010135



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2003

Dear Mr. Brown:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-04n	Applicant #:	2003-20XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



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OR120018_BR_010136



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 22, 2003

Dear Mr. Ames:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-04n Applicant #: 2003-20XRAB
Received: January 21, 2003 Effective: February 20, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: ID KS MO MT WA
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPO, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date:

1/24/03

State:

Montana

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2003

Dear Mr. Wessels:

Enclosed is notification 03-021-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-04n Applicant #: 2003-20XRAB
Received: January 21, 2003 Effective: February 20, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: ID KS MO MT WA
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/27/03

State: WA

Rptloc01/R4



APHIS Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010138

JAN 27 2003

February 6, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 20, 2003.

Interstate movement and Release
Notification no. 03-021-04n (2003-20XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Cooper, Idaho State Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 03-021-04n

OR120018_BR_010139

Confirmation Report-Memory Send

Time : Feb-06-03 05:42pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 341
Date : Feb-06 05:40pm
To : 916367377085
Document Pages : 05
Start time : Feb-06 05:40pm
End time : Feb-06 05:42pm
Pages sent : 05
Job number : 341

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 6, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 20, 2003.

Interstate movement and Release
Notification no. 03-021-04n (2003-20XKAB)
Regulated article - wheat
Destinations - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,
(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Cooper, Idaho State Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA



APHIS: Protecting American Agriculture

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OR120018_BR_010140

SAMPLE NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): 03-021-042 Crop: WHEAT
Applicant's Name: MONSANTO Trait/Gene: GLYPHOSATE-RESISTANT
Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)
Location of Site: (b) (4) Date of Inspection: 08-06-03
Type of Location: (b) (4) IDAHO Nursery Research X Other (Describe)
GPS Coordinates: (b) (4) Latitude (b) (4) Longitude (b) (4)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Y N

B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Y N

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y N

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? Y N

C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.

 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N

 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? Y N

 3. Terminating the experiment before flowering.
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N

X 4. Physical isolation.
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? Y N

 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N

- D. If the applicant's design standards use border rows, are there the state number of border rows? N.A.
Y N
- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Y
Y N
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? N.A.
Y N
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y
Y N
- H. Was the field site marked as stated in the design standards? Y
Y N
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y
Y N
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y
Y N

III. Devitalization.

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y
Y N
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)

Location of PPQ Office Box 67, Twin Falls ID 83303

Names and Affiliation of Any Other Persons at the Inspection:

(b) (6), (b) (7)(C), (b) (4) MONSANTO

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.

Thursday, August 21, 2003

Tony Roman, Ralph Stoaks

Tony and Ralph,

I'm sorry to send this report so late. Since the date of inspection, I have repeatedly asked Dr. Hermann to provide a map of the site. None has been received to date, so I'm sending this to you with no map.

(b) (6), (b) (7)(C), (b) (4)

Louis Dersch
PPQ Officer

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-20XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-04n

1. USDA Reference Number

2. Application Reference Number 2003-20XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

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Monsanto Reference ID
2003-20XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-20XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From/Ship To:

ID

* (b)(4) Bingham County/Province, ID, (b)(4) USA

CONTACT (b)(4), (b)(6), (b)(7)(C) ID (b)(4), (b)(6), (b)(7)(C)
USA (b)(4), (b)(6), (b)(7)(C)

J-CBI

* (b)(4) Bannock
County/Province, ID (b)(4) USA

CONTACT (b)(4), (b)(6), (b)(7)(C) ID (b)(4), (b)(6), (b)(7)(C)
USA (b)(4), (b)(6), (b)(7)(C) FAX (b)(4), (b)(6), (b)(7)(C)

J-CBI

* (b)(4) Latah County/Province,
ID, (b)(4) USA

CONTACT (b)(4), (b)(6), (b)(7)(C) ID (b)(4), (b)(6), (b)(7)(C) USA,
(b)(4), (b)(6), (b)(7)(C)

J-CBI

(b)(4), (b)(6), (b)(7)(C)

* (b)(4) Twin Falls County/Province, ID (b)(4) USA

CONTACT (b)(4), (b)(6), (b)(7)(C) ID (b)(4), (b)(6), (b)(7)(C)
USA (b)(4), (b)(6), (b)(7)(C)

(b)(4), (b)(6), (b)(7)(C)

CONFIDENTIAL

Monsanto Reference ID
2003-20XRAB

J-CBI

(b) (4)

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

J-CBI

(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2003-20XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(4)

ID

(b) (4) Bingham County/Province ID (b) (4) USA 5 acres.
(b) (4) (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA

] -CBI

(b) (4) Bannoc
(b) (4) (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA

] -CBI

(b) (4)

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-021-04n **Monsanto #2003-20XRAB**

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317251	Bingham	ID	
2147312700	Bannock	ID	
2147312358	Latah	ID	Not Planted
2147312359	Latah	ID	Not Planted

Bingham County/ID (2147317251)

(b) (4)

apl
4/26/04

(b) (4)

Bannock County/ID (2147312700)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-021-04n Monsanto #2003-20XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317251	Bingham	ID	
2147312700	Bannock	ID	
2147312358	Latah	ID	Not Planted
2147312359	Latah	ID	Not Planted

Bingham County/ID (2147317251)

Planting Date: 04/16/2003

Harvest Date: 10/24/2003

Destruct Date: 10/24/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bannock County/ID (2147312700)

Planting Date: 05/06/2003

Destruct Date: 06/15/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/22/03 10:27 am

Notification Tracking Sheet

=====

Bp number: 03-021-05n

=====

App number: 2003-24XRAB Begin movement: 2/15/03
 Received: 1/21/03 End movement: 2/15/04
 Institution: Monsanto Begin release: 2/15/03
 Recipient: Wheat End release: 2/15/04
 Status: Pending Acre: 10.00
 Effective date: 2/20/03 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: **(b) (6), (b) (7)(C)**
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ayd</i>] | [1/22/03] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>VM</i>]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLN</i>] | [1/23/03]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*
Interstate	*Dest*	MN	*	*NER	*
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	ND	*	*SCR	*
Interstate	*Dest*	SD	*	*SCR	*
Interstate	*Orig*	KS	*	*SCR	*
Interstate	*Orig*	MN	*	*NER	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	ND	*	*SCR	*
Interstate	*Orig*	SD	*	*SCR	*
Release	*	*MN	*	1*NER	*

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ayd</i>] | [1/23/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLN</i>] | [3/13/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLN</i>] | [3/14/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-24XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-05n

1. USDA Reference Number

2. Application Reference Number 2003-24XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-24XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2003-24XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of grain may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND, SD

DESTINATION:

KS, MN, MO, ND, SD

Ship From/Ship To:

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MN

* (b) (4) Ramsey County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Polk County/Province, MN, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID
2003-24XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Ramsey County/Province,
MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

ND

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] -CBI

SD

* (b) (4) Brookings
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-24XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[REDACTED] (b) (4) Polk County/Province, MN, (b) (4)
U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-24XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-24XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-05n

1. USDA Reference Number

2. Application Reference Number 2003-24XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-24XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-24XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of grain may be shipped for the duration of this notification. Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND, SD

DESTINATION:

KS, MN, MO, ND, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-24XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-24XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 16, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-24XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-05n

1. USDA Reference Number

2. Application Reference Number 2003-24XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-24XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-24XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-24XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 16, 2003

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 22, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-05n	Applicant #:	2003-24XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010174

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 22, 2003

Dear Dr. Hanks:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-05n	Applicant #:	2003-24XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010175

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2003

Dear Mr. Brown:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-05n	Applicant #:	2003-24XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010176

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 22, 2003

Dear Mr. Nelson:


Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-05n	Applicant #:	2003-24XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010177

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 22, 2003

Dear Mr. Fridley:


Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-05n Applicant #: 2003-24XRAB
Received: January 21, 2003 Effective: February 20, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010178



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

faxed 3-10-03

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 22, 2003

Dear Dr. Hanks:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-05n Applicant #: 2003-24XRAB
Received: January 21, 2003 Effective: February 20, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,
(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination *with the attached additional conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *3-10-03*

State: *MN*

Rptloc01/R4





Minnesota Department of Agriculture

(651) 296-1277

March 10, 2003

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 03-021-05n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
 - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains) should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2003.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Banks, Ph.D.
State Biotechnologist



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 22, 2003

Dear Mr. Nelson:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-05n Applicant #: 2003-24XRAB
Received: January 21, 2003 Effective: February 20, 2003
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3/10/03

State: ND

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010181

MAR 12 2003

MAR 12 2003 9:43AM

NO. 937 P. 2



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 22, 2003



Dear Mr. Fridley:

Enclosed is notification 03-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	03-021-05n	Applicant #:	2003-24XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PRQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 1/24/03

State: South Dakota

Rptloc01/R4



APHIS: Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010182

JAN 24 2003

March 13, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 13, 2003.

Interstate movement and Release

Notification no. 03-021-05n (2003-24XRAB)

Regulated article - Wheat

Destinations - Kansas, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concurs with APHIS determination, with the attached additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 03-021-05n

OR120018_BR_010183

Confirmation Report-Memory Send

Time : Mar-14-03 01:04pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 828
Date : Mar-14 01:02pm
To : 916367377085
Document Pages : 05
Start time : Mar-14 01:02pm
End time : Mar-14 01:04pm
Pages sent : 05
Job number : 828

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverside, Maryland
20737-1236

March 13, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 13, 2003.

Interstate movement and Release
Notification no. 03-021-05n (2003-24KRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010184



United States
Department of
Agriculture

August 5, 2003

Animal and Plant
Health Inspection
Service

Plant Protection
and Quarantine

7150 Humphrey Drive
Suite 2189
Minneapolis MN 55450

Phone: (612) 725-1771
Fax: (612) 725-1741

W. Scott Wood
USDA, APHIS, PPQ
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Mr. Wood,

On July 29, 2003 I inspected field release notification site 03-021-05n (b) (6), (b) (7)(C), (b) (4) accompanied me.

The attached questionnaire summarizes that inspection. The plot will be harvested by plot combine (b) (6), (b) (7)(C), (b) (4) and I discussed the MDA requirement of monitoring the field plus a 33 ft isolation area surrounding the plot for two years.

(b) (6), (b) (7)(C)

Scott Smith

8/20/03



APHIS Protecting American Agriculture

Equal Opportunity Employer

OR120018_BR_010185

APHIS Notification Number(s): 03-021-05n Crop: Wheat
Applicant's Name: Monsanto Trait/Gene: HT
Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)
Location of Site: (b) (6), (b) (7)(C), (b) (4) MN Date of Inspection: 7/29/03
Type of Location: Farm _____ Nursery _____ Research X Other _____ (Describe) _____
GPS Coordinates (If available): Latitude (b) (6), (b) (7)(C), (b) (4) Longitude (b) (6), (b) (7)(C), (b) (4)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Yes
B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Yes

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Another transgenic trial (03-023-14n) located adjacent but >3M
B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? All fallow areas kept clean; grassy edges mowed
C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---|
| _____ 1. Removing flowers. | | |
| C.1. Is there any evidence that the plants have flowers or that flowers have been removed? | Y | N |
| _____ 2. Bagging flowers/tassels | | |
| C.2. Does the applicant have material to bag reproductive structures? | Y | N |
| _____ 3. Terminating the experiment before flowering. | | |
| C. 3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? | Y | N |
| <u>X</u> 4. Physical isolation. | | |
| C. 4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? | Yes | |
| _____ 5. Temporal isolation. | | |
| C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? | Y | N |
- D. If the applicant's design standards use border rows, are there the state number of border rows?
NA

- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Yes, alleys. All plants treated as transgenics.
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? NA
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Yes
- H. Was the field site marked as stated in the design standards? Small flags within plot
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Yes
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Yes

III. Devitalization.

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Material not shipped will be buried
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: Scott Smith

Phone: 612 725 1771

Location of PPQ Office: Minneapolis

Names and Affiliation of Any Other Persons at the Inspection:

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.

CONFIDENTIAL

2003 Wheat Field Test Report

USDA

Monsanto #2003-24XRAB

Not A FOIA Deletion

April 23, 2004

**Biotech Field Compliance Team
Monsanto Company**

Location

2147301548

County

Polk

State

MN

Polk County/MN (2147301548)

(b) (4)

oib
4/26/04

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-021-05n Monsanto #2003-24XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147301548	Polk	MN

Polk County/MN (2147301548)

Planting Date: 05/01/2003

Harvest Date: 08/14/2003

Destruct Date: 08/27/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

1/22/03 10:27 am

Notification Tracking Sheet

=====
Bp number: 03-021-24n
=====

App number: 2003-55XRAB
Received: 1/21/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/20/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/15/03
End movement: 2/15/04
Begin release: 2/15/03
End release: 2/15/04
Acre: 15.00
CBI status: CBI
Fax: 636-737-7085

- =====
- | | Initial | Date |
|--------------------------------------------------------------------------------|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ayd] | [1/22/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [fmk]* | [1/23/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLn] | [1/24/03]* |
| 4. [] State response | | |

- | | O/d | Loc | Site | Reg | | |
|------------|--------|-----|------|------|---|-----|
| Interstate | *Dest* | MO | * | *SCR | * | [] |
| Interstate | *Dest* | WA | * | *WR | * | [] |
| Interstate | *Orig* | MO | * | *SCR | * | [] |
| Interstate | *Orig* | WA | * | *WR | * | [] |
| Release | * | *WA | * | 3*WR | * | [] |
5. ☒ Enter genes into database [ayd] [1/23/03]
6. ☒ Letter of acknowledgement/denial/withdraw [KLn] [1/27/03]*
7. ☒ Enter final data into database [KLn] [1/28/03]
8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-55XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-24n

1. USDA Reference Number

2. Application Reference Number 2003-55XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C), (b) (4)

Phone

(b) (6), (b) (7)(C), (b) (4)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C), (b) (4)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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Monsanto Reference ID
2003-55XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoV₃/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-55XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

5,000 Ship up to _5,000_pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From/Ship To:

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

WA

*[REDACTED] (b) (4) Adams County/Province, WA,
(b) (4) Adams

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

*[REDACTED] (b) (4) Whitman County/Province, WA, (b) (4)
USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

*[REDACTED] (b) (4) Whitman
County/Province, WA, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2003-55XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Lincoln County/Province, WA,
(b) (4) Lincoln

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-55XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

(b) (4) Adams County/Province, WA,
(b) (4) Adams, 4.0 acres. (2147314278)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Whitman County/Province, WA, (b) (4)
USA, 5.5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Lincoln County/Province, WA, (b) (4)
Lincoln, 5.5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

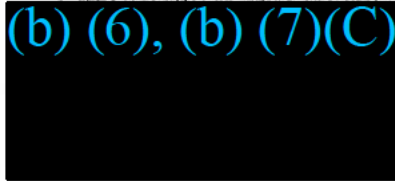
Monsanto Reference ID

2003-55XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-55XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-24n

1. USDA Reference Number

2. Application Reference Number 2003-55XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 15, 2003 - February 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-55XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-55XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/15	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

5,000 Ship up to _5,000_pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, Adams

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Lincoln County/Province, WA, Lincoln

CBI-DELETED

Monsanto Reference ID
2003-55XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

[CBI Deleted] -- Adams County/Province, WA, Adams, 4.0 acres.

[CBI Deleted] -- Whitman County/Province, WA, USA, 5.5 acres.

[CBI Deleted] -- Lincoln County/Province, WA, Lincoln, 5.5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

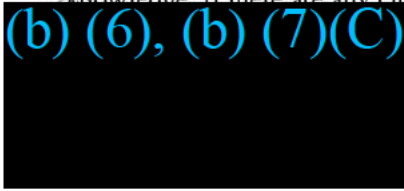
<http://www.monsanto.com>

Monsanto Reference ID
2003-55XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-55XRAB

Permit Unit

January 16, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-021-24n

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2. Application Reference Number 2003-55XRAB

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Phone

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Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

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5. Recipient

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Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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Monsanto Reference ID
2003-55XRAB

designation of transformed line: 33391

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CBI

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CBI-DELETED

Monsanto Reference ID
2003-55XRAB

7. Mode of Transformation

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ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, Adams

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Lincoln County/Province, WA, Lincoln

CBI-DELETED

Monsanto Reference ID
2003-55XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(3)

WA

[CBI Deleted] -- Adams County/Province, WA, Adams, 4.0 acres.

[CBI Deleted] -- Whitman County/Province, WA, USA, 5.5 acres.

[CBI Deleted] -- Lincoln County/Province, WA, Lincoln, 5.5 acres.

MONSANTO



CBI-DELETED

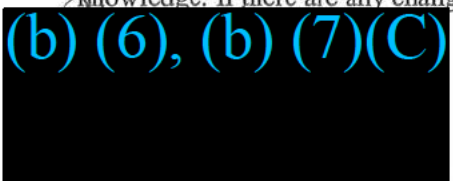
Monsanto Reference ID
2003-55XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 16, 2003

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2003

Dear Mr. Brown:

Enclosed is notification 03-021-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-24n	Applicant #:	2003-55XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010213

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2003

Dear Mr. Wessels:

Enclosed is notification 03-021-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-021-24n	Applicant #:	2003-55XRAB
Received:	January 21, 2003	Effective:	February 20, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010214



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2003

Dear Mr. Wessels:

Enclosed is notification 03-021-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-021-24n
Received: January 21, 2003
Institution: Monsanto
Interstate destination: MO WA
Release destination: WA

Applicant #: 2003-55XRAB
Effective: February 20, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/27/03

State: WA

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_010215

JAN 27 2003

January 27, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 20, 2003.

Interstate movement and Release
Notification no. 03-021-24n (2003-55XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 03-021-24n

OR120018_BR_010216

Confirmation Report-Memory Send

Time : Jan-28-03 12:21pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 193
Date : Jan-28 12:20pm
To : 916367377085
Document Pages : 02
Start time : Jan-28 12:20pm
End time : Jan-28 12:21pm
Pages sent : 02
Job number : 193

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

January 27, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 20, 2003.

Interstate movement and Release
Notification no. 03-021-24n (2003-55XRB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010217

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

Three
different
crops
Same
NOT.

PERMIT NUMBER 03-021-24n CROP Wheat
ORGANIZATION / COMPANY Monsanto (b) (6), (b) (7)(C), (b) (4)
LOCATION (b) (6), (b) (7)(C), (b) (4) WA.

DATE OF PPQ NOTIFIED OF HARVEST _____ ACTUAL HARVEST DATE 8/20/03

DATE OF HARVEST INSPECTION 9/5/03

HOW WAS CROP TERMINATED? Harvested with small plot combine

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Minimal tillage followed by spraying herbicide (Assure II). 180-900 gram packets of seed will be stored in a locked cabinet at the Washington State University Plant Growth Facility. All regulated seed will be analysed for protein and yield weights and then autoclaved upon completion of the research.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor used to clean combine and all equipment associated with harvest of regulated material

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? NO WHERE? _____

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE Yes

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? Monitor 2 years for volunteers.

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? Yes, * Crop verify an independent third party auditor hired by Monsanto was present during planting and harvest.

INSPECTING PPQ OFFICER George Bruno PHONE (509) 353-2950
LOCATION OF PPQ OFFICE SPokane, WA

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

(b) (6), (b) (7)(C)

(b) (6), (b) (7)

apl
9/24/03

REVISED 01/24/97

* Original sent to BRS

OR120018_BR_010218

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-021-24n CROP Wheat
ORGANIZATION / COMPANY Monsanto (b) (6), (b) (7)(C), (b) (4)
LOCATION (b) (6), (b) (7)(C), (b) (4)
DATE OF PPQ NOTIFIED OF HARVEST _____ ACTUAL HARVEST DATE 7/31/03
DATE OF HARVEST INSPECTION 9/5/03
HOW WAS CROP TERMINATED? Harvested with small plot combine

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Combination of tillage and herbicide spray (Assure II). 180-400 gram packets of seed will be stored in a locked cabinet at the Washington State University plant growth facility. All regulated seed will be tested for protein and yield weights and then autoclaved upon completion of the study.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor used to clean combine and all equipment associated with harvest of regulated material

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? NO WHERE? _____

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE Yes

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? Monitor 2 years for volunteers.

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? Yes, *Crop Verity an independent third party auditor contracted by Monsanto was present during planting and harvest.

INSPECTING PPQ OFFICER George Bruno PHONE (509) 353-2950
LOCATION OF PPQ OFFICE SPOKANE, WA

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

(b) (6), (b) (7)(C)

(b) (6), (b) (7)

REVISED 01/24/97

Original sent to BRS

OR120018_BR_010219

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-021-24n CROP wheat
ORGANIZATION / COMPANY Monsanto (b) (6), (b) (7)(C), (b) (4)
LOCATION (b) (4), WA

DATE OF PPQ NOTIFIED OF HARVEST _____ ACTUAL HARVEST DATE 8/27/03

DATE OF HARVEST INSPECTION 9/17/03

HOW WAS CROP TERMINATED? Harvested with small plot combine

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

Minimal tillage followed by spraying herbicide (Assure II). 260-1500 gram packets of seed will be stored in a locked cabinet at the Washington State University Plant Growth Facility. All regulated seed will be tested for protein and yield weights and then autoclaved upon completion of the study.

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Air compressor used to clean combine and all equipment associated w/ harvest of regulated material.

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? No WHERE? * A small amount of regulated seed may be shipped to ST Louis, Missouri and then Hawaii for seed increase next month.

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? Monitor 2 years for volunteers

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes, * Crop Verify an independent third party auditor contracted by Monsanto was present during planting and harvest.

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LOCATION OF PPQ OFFICE SPOKANE, WA

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

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(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

REVISED 01/24/97

* Original sent to BRS

OR120018_BR_010220

CONFIDENTIAL

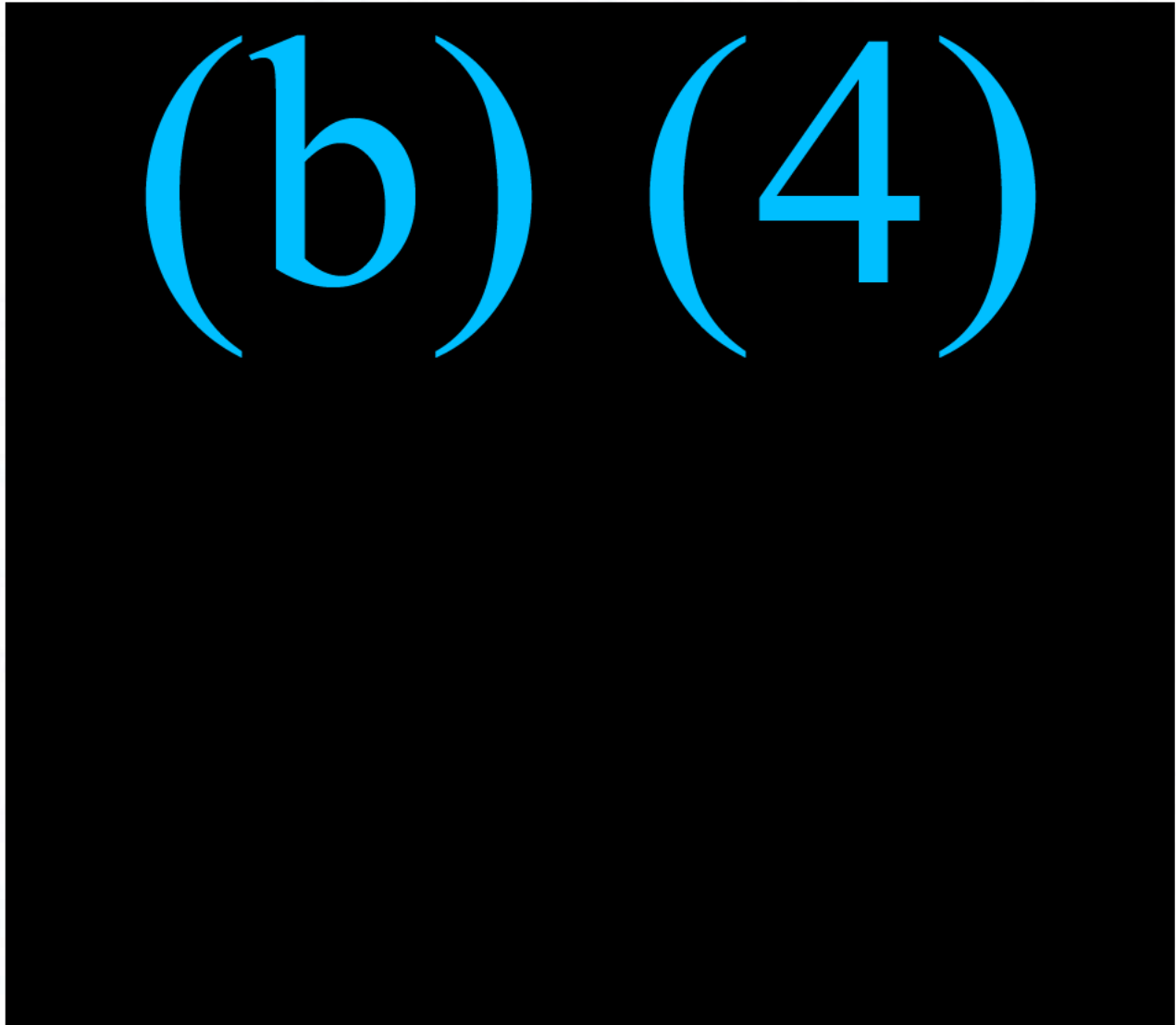
2003 Wheat Field Test Report
USDA #03-021-24n **Monsanto #2003-55XRAB**

April 7, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147314278	Adams	WA
2147306763	Whitman	WA
2147317254	Lincoln	WA

Adams County/WA (2147314278)



apl
4/8/04

(b) (4)

Whitman County/WA (2147306763)

(b) (4)

Lincoln County/WA (2147317254)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-021-24n Monsanto #2003-55XRAB

April 7, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147314278	Adams	WA
2147306763	Whitman	WA
2147317254	Lincoln	WA

Adams County/WA (2147314278)

Planting Date: 03/21/2003

Harvest Date: 07/31/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Whitman County/WA (2147306763)

Planting Date: 05/07/2003

Harvest Date: 08/27/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Lincoln County/WA (2147317254)

Planting Date: 04/25/2003

Harvest Date: 08/20/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

1/22/03 10:27 am

Notification Tracking Sheet

=====

Bp number: 03-022-01n

=====

App number: 2003-23XRAB
Received: 1/22/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/21/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/16/03
End movement: 2/16/04
Begin release: 2/16/03
End release: 2/16/04
Acre: 50.00
CBI status: CBI

Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[aip]	[1/22/03]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[LMK]*	[1/23/03]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLN]	[1/24/03]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	MT	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	MT	*	*WR *
Release	*	*MT	*	6*WR *

5. <input checked="" type="checkbox"/> Enter genes into database	[aip]	[1/23/03]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw	[KLN]	[1/28/03]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLN]	[1/24/03]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

Permit Unit

January 17, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-022-01n

1. USDA Reference Number

2. Application Reference Number 2003-23XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 16, 2003 - February 16, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

1-4/5/13
F: PW/mst
all

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Monsanto Reference ID
2003-23XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-23XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10,000 pounds of seed may be shipped for the duration of this notification. Ship up to 5000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT

DESTINATION:

KS, MO, MT

Ship From/Ship To:

KS

* (b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

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Monsanto Reference ID
2003-23XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4) Cascade County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4), (b) (6), (b) (7)(C) Judith Basin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

*[(b) (4) Yellowstone
County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

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Monsanto Reference ID
2003-23XRAB

* [REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C)
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

* [REDACTED] (b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C), USA,
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

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Monsanto Reference ID
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Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(6)

MT

(b) (4) Gallatin County/Province, MT (b) (4) USA, 10
acres. (2147307561)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA, 5
acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Judith Basin County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Yellowstone
County/Province, MT, (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-23XRAB

[(b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 5
acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) SA (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

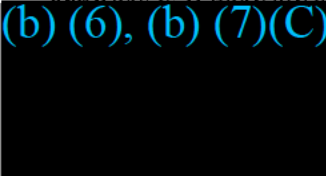
<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 17, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

Permit Unit

January 17, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-022-01n

1. USDA Reference Number

2. Application Reference Number 2003-23XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 16, 2003 - February 16, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

Handwritten notes:
I: or
6/5/13
all
new/mt

CBI-DELETED

Monsanto Reference ID
2003-23XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-23XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10,000 pounds of seed may be shipped for the duration of this notification. Ship up to 5000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT

DESTINATION:

KS, MO, MT

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

[CBI Deleted] -- *Yellowstone County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2003-23XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(6)

MT

- [CBI Deleted] -- Gallatin County/Province, MT, USA, 10 acres.
- [CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres.
- [CBI Deleted] -- Pondera County/Province, MT, USA, 10 acres.
- [CBI Deleted] -- Judith Basin County/Province, MT, USA, 10 acres.
- [CBI Deleted] -- Yellowstone County/Province, MT, USA, 10 acres.
- [CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 17, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

Permit Unit

January 17, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-022-01n

1. USDA Reference Number

2. Application Reference Number 2003-23XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

February 16, 2003 - February 16, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar Bobwhite

*2 = 4/5/13
I: DW/not
file*

CBI-DELETED

Monsanto Reference ID
2003-23XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase~~ gene (CP4) from an **Agrobacterium** species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

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Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase~~ gene (CP4) from an **Agrobacterium** species, strain CP4.

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CBI-DELETED

Monsanto Reference ID
2003-23XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 10,000 pounds of seed may be shipped for the duration of this notification. Ship up to 5000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT

DESTINATION:

KS, MO, MT

Ship From/Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

[CBI Deleted] -- *Yellowstone County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Cascade County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2003-23XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(6)

MT

[CBI Deleted] -- Gallatin County/Province, MT, USA, 10 acres.

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres.

[CBI Deleted] -- Pondera County/Province, MT, USA, 10 acres.

[CBI Deleted] -- Judith Basin County/Province, MT, USA, 10 acres.

[CBI Deleted] -- Yellowstone County/Province, MT, USA, 10 acres.

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres.

MONSANTO



CBI-DELETED

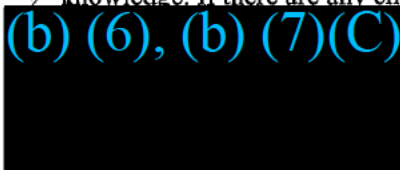
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-23XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 17, 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 22, 2003

Dear Mr. Sim IV:

Enclosed is notification 03-022-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-022-01n	Applicant #:	2003-23XRAB
Received:	January 22, 2003	Effective:	February 21, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

Handwritten: 1-6/15/13
Signature: [illegible]



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An Equal Opportunity Employer

OR120018_BR_010250



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2003

Dear Mr. Brown:

Enclosed is notification 03-022-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-022-01n	Applicant #:	2003-23XRAB
Received:	January 22, 2003	Effective:	February 21, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

Handwritten: 1-4/5/13
lll



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OR120018_BR_010251

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 22, 2003

Dear Mr. Ames:

Enclosed is notification 03-022-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-022-01n	Applicant #:	2003-23XRAB
Received:	January 22, 2003	Effective:	February 21, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010252

*2-1-03
Dw/mt
Rec 4/5/03*



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

January 22, 2003

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

Dear Mr. Ames:

Enclosed is notification 03-022-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-022-01n
Received: January 22, 2003
Institution: Monsanto
Interstate destination: KS MO MT
Release destination: MT

Applicant #: 2003-23XRAB
Effective: February 21, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date: 1/27/03

State: Montana

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_010253

JAN 27 2003

Handwritten:
J. I. Bure
Dw/Not
6/15/13

January 28, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2003.

Interstate movement and Release
Notification no. 03-022-01n (2003-23XRAB)
Regulated article - Wheat
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/s/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
File number 03-022-01n

2-6/15/13
I: DWT/mk
m

OR120018_BR_010254

2/23/04
Appendix 1.5A

Pharmaceutical/Industrial Harvest report worksheet

(b) (6), (b) (7)(C), (b) (4)



*I: put back
2/13/13 kll*

Yes

No

Report contains a significant deficiency ☐

☐

☐

(b) (6), (b) (7)(C), (b) (4)



WESTERN REGION
NOTIFICATION INSPECTION WORKSHEET
regarding 340.3(c)

07/18/03

0302-01N

Non-Hybrid

BIOTECH NUMBER: 2003-23XRAE CROP Wheat DATE PLANTED 5/14/03

APPLICANT: (b) (6), (b) (7)(C) COMPANY Monsanto Company

COOPERATOR CONTACT PERSON (b) (6), (b) (7)(C), (b) (4) TEL/FAX 406-994-7987

SITE LOCATION (b) (6), (b) (7)(C), (b) (4) Judith Basin County MT
(address) (b) (6), (b) (7)(C), (b) (4)

DATE OF INSPECTION 6/19/03

Inspection Team, (1) PPQO Kimberly D. Merenz

(2) Applicant Montana State Univ.

Check one:

Cooperator (3) State (b) (6), (b) (7)(C), (b) (4)
MSU Grad Student

☐ Field Release ☐ Harvest ☒ Monitor

SUMMARY OF PERFORMANCE STANDARDS Refer to User's Guide for Submitting Notifications for inspection protocols, i.e., crop isolation distances and outcross prevention.

1. Did viable plant material escape during shipping or at destination? (Ex. Shipping container should be sturdy and have notification number written on outside). Yes ☐ No ☒
2. Separation is maintained between regulated plant material and non regulated plant material to prevent mixing (Note isolation distances and border rows in User's Guide). Yes ☒ No ☐
- 3a. Identity of plant material was maintained while in use? (Plot maps and attention to marked reference points to identify volunteers in spring after test plot is gone). Yes ☒ No ☐

THESE STANDARDS PERTAIN MAINLY TO MATURE PLANTS

- 3b. Plant material is being contained (Ex: all material harvested or devitalization was by burning). Yes ☐ No ☐
4. The researcher/cooperator must advise you if crown gall is present after planting. Was it reported as being present? Yes ☐ No ☐
5. Field trial is being conducted in manner to avert persistence in the environment (controlling pollination, etc.)? Yes ☐ No ☐
6. Upon termination, was material handled to prevent volunteers? Yes ☐ No ☐

INSPECTING PPQ OFFICER (b) (6), (b) (7)(C)

PHONE (406) 449-5210

LOCATION OF PPQ OFFICE Helena MT

Any other pertinent information the inspecting officer can furnish is appreciated.

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

REVISED 01/24/97

8-1-03
P. W. H. 13
4/15/03
all

(b) (6), (b) (7)(C), (b) (4)



**Department of Land Resources and Environmental Sciences**

334 Leon Johnson Hall
MSU • Bozeman
P.O. Box 173120
Bozeman, MT 59717-3120
Telephone (406) 994-7060
Fax (406) 994-3933

SENT: OKAY
NO

RECEIVER:	(b) (6), (b) (7)(C), (b) (4)		
ADDRESS:			TELEPHONE:
		406 449-5210	
FAX NUMBER:	406 449-5212	NO. PAGES (including cover pg.):	5
SENDER:	(b) (6), (b) (7)(C), (b) (4)		
DATE:	June 26 2003	TELEPHONE:	(b) (6), (b) (7)(C), (b) (4)
Index #:			

(Transmitting from Canon 7500 Facsimile Machine. If all pages not received, call 406-994-7060)

WHEAT FIELD RELEASE

PERFORMANCE STANDARDS

Notification to allow movement of material regulated by the USDA-APHIS must be in place prior to shipment. This includes shipment of the seed (or other plant material) to a site to initiate a field trial as well as shipment of harvested seed (or other plant material) from a field trial site to another location. Harvested commodities from field trials of regulated plant material must not be allowed to enter commerce as a food or feed product.

Shipping

When shipping, all packages must be clearly labeled as to content and the USDA notification number must be prominently displayed on the outer package (for example, USDA #00-000-00n, Wheat).

Regulated plant materials shipped will include any viable plant parts as described in the notification. For most plant material, any shipping container that consists of an inner container that is a sturdy bag, box, or other such structure, enclosed in an outer container that is also a sturdy bag, box, or other such structure is acceptable under most circumstances. Both inner container and outer container must be capable of preventing seed or material loss.

If transfer of the regulated material is to take place within the state and is not noted on the notification, the state regulatory official must be contacted before the movement may occur. The name and the phone number of the state official to contact can be found in the letter immediately after the cover page in the compliance packet.

Maintenance at Destination

When regulated material is received at contained facilities, such as storage rooms or greenhouses, it should be handled and stored in such a way that there is no release into the environment (for example, stored in a locked file or storage cabinet). This requires ensuring that regulated material is not accidentally mixed with non-regulated material, does not transfer genes to non-regulated material inside or outside the facility, and does not accidentally escape from the contained facility.

To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as obvious marks, color-coding, or strict segregation of material should be implemented.

Seed and/or other plant material that will be planted directly in the field should be kept secure until needed for planting. If excess seed and/or plant material exists after planting, this material should be devitalized using suitable means as given in the "Devitalization" section of this document or returned to the contained facility. To minimize pollen-mediated gene flow out of a contained facility, physical barriers or methods such as sterilization or bagging should be used. Similar methods should be used to prevent pollen flow to receptive plants within the contained facility as well.

Persistence in the Environment

To prevent the regulated material in the field trial from persisting in the environment, devitalization treatments given in the "Devitalization" section of this document, should be utilized. To prevent offspring from being formed and persisting, means must be taken to minimize the likelihood of pollination and successful fertilization of receptive plants outside the field trial area.

The following are minimum standards of isolation that will minimize the likelihood of pollination of receptive wheat, durum or triticale plants outside of the field trial area:

- 1) A minimum isolation distance of 33 feet (10 M) must be maintained between the trial and any wheat, durum or triticale planting that will produce seed to be saved for seed production.

The isolation area from the trial can be:

Wheat Performance Standards (Cont'd)

- * Fallow or bare ground
- * Crops other than small grains
- * Physical isolation such as road ditches, farmsteads, fence rows, wind breaks, etc.

OR

2) Destruction of the wheat trial prior to flowering.

When the field trial is located on a privately-owned farm, the responsible researcher must inform the owner of the farm as to the nature of the experiment and the need to maintain these plants and seed separately from any other plant material that is not part of the trial. The cooperator and/or owner should be instructed as to the need to frequently observe the plots for any signs of crop damage or vandalism and immediately report any such acts to Monsanto.

Inadvertent Mixing of Materials in Environmental Releases

Inadvertent mixing of regulated material and non-regulated wheat should be avoided. Inadvertent mixing may be prevented by planting each regulated article in a defined area with an unplanted alley between it and any other material. The width of this alley will vary depending on the method of harvesting and other operations. For machine harvesting, the alley should be wide enough to allow for machine movement without mechanical mixing. **All machinery (planting, maintenance, and harvesting) that may retain viable plant material should be cleaned after use in the regulated field, and before moving the equipment out of the regulated field. This will ensure that any regulated material retained by machinery will remain in the regulated field.**

For all plantings, identity must be maintained by planting regulated plants in distinct plots. Clearly stake out the plot, including border rows with easily identifiable markers (for example, metal or wooden stakes). It should remain clearly identified for the duration of the volunteer monitoring period. The use of stakes or markers to define the area where the regulated plants are grown will help in identifying volunteers for later elimination.

Devitalization

In a contained facility, seed and other material capable of natural propagation should be devitalized before leaving the contained facilities and/or placed in suitable containers prior to being shipped to another facility (see "Shipping") to prevent accidental release in the environment. Suitable means of devitalization at contained facilities include the use of:

- * dry or steam heat
- * physical grinding
- * chemicals or
- * composting (at a location that can be monitored until devitalization occurs).

In an environmental release, plant material or seed may also be disposed of according to the conditions of your field project plan/protocol. For example, send seed back to the origination point, or to post-harvest location(s) in appropriate containers, bury or disk in the field plot, etc. Final disposition and devitalization, after harvest, may also be achieved by one of the following methods: hand weeding, grinding, incineration, chemical application or mechanical cultivation. In some cases, the remaining vegetative material in the field can be incorporated into the soil and left to natural devitalization by the elements. These requirements apply to the entire plot area, including the border rows.

Wheat Performance Standards (Cont'd)**Post-Harvest Monitoring for Volunteer Plants**

The area (plot area including border rows) must be monitored for volunteers and all volunteers must be destroyed. Volunteers can be minimized by growing regulated material in defined areas in the field and by utilizing adequate termination protocols. **Wheat trials destroyed before flowering still require volunteer monitoring due to seed dormancy.**

After field trial completion, plots will be monitored for a period of twenty-four (24) months. If volunteers are still present at the last monitoring time, continue to monitor for volunteers and contact your compliance specialist.

Volunteers will be removed prior to seed set or flowering. Methods that can be used to eliminate volunteers include tillage, herbicide application, and hand weeding.

Arrangements must be made to allow access to the land for the volunteer-monitoring period.

Replanting of the field trial plot during the next field season must be done in such a manner as to allow for appropriate volunteer monitoring. Options for replanting the test and border row areas are:

- * Leave the site fallow and control any volunteer plants.
- * Plant to another appropriate rotational crop which would allow the clear identification and control of volunteer wheat plants.
- * Plant to regulated wheat and follow the requirements for that regulated wheat material.
- * If planting to a non-regulated crop of the same species, the rules for field testing a regulated field trial must be followed.

The following requirements must be met in continuous nursery situations, as in Hawaii and Puerto Rico:

- * The field should remain fallow for a minimum of 30 days or an additional time period mandated by the State Department of Agriculture. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Then the volunteer wheat should be destroyed. Any additional requirements mandated by the State Department of Agriculture must be met.

Compliance

The site responsible researcher must:

- 1) Comply with all applicable requirements set forth in this Crop Performance Standard.
- 2) Have the Crop Performance Standard available during a USDA inspection.
- 3) Notify the Monsanto compliance specialist within 24 hours of any compliance violation or unintentional release of regulated material.

If a compliance violation or unintentional release occurs, stabilize the situation first, then gather information and call the compliance specialist. The proper agency authorities will then be contacted by the Monsanto Compliance Team, as required.

Examples of compliance violations:

- * Allowing regulated material to enter commerce
- * Failure to adhere to isolation requirements, as described in Crop Performance Standard
- * Failure to have the Crop Performance Standard available during a USDA inspection

Wheat Performance Standards (Cont'd)

- * Feeding of regulated plant material to livestock
- * Failure to monitor for volunteers
- * Planting without an approved notification
- * Conducting trial activities outside of the approved dates of the notification
- * Moving planting or harvesting equipment from the plot site before cleaning
- * Mixing regulated plant material with non-regulated plant material
- * Planting at an unapproved site or in an unapproved state
- * Planting more acreage than approved on the notification
- * Shipping to an unapproved location or to an unapproved state
- * Loss of seed by shipping company, applicant or designated representative
- * Movement of seed or regulated plant material outside the test area by natural causes (floods, tornadoes, etc.)



United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine



USDA, APHIS, PPQ
1220 Cole Ave.
Helena, MT 59601
(406) 449-5210
Fax: 449-5212

Federal Relay Service (Voice/TTY/ASCII/Spanish) 800-877-8339

Subject: Notification Field Site Inspection [REDACTED]

Date: September 4, 2003

To: Juan A. Roman, Chief, Biotechnology Program Operations
USDA APHIS BRS
4700 River Rd. Unit 147, 5B53
Riverdale MD 20737

On 13 August 2003 I conducted a Notification Field Site Inspection at the [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] (b) (6), (b) (7)(C), (b) (4) MT (site # 03-022-01n).

Prior to the inspection I called [REDACTED] (b) (6), (b) (7)(C) Monsanto Company, 408 Deer Drive, Great Falls MT 59404, [REDACTED] (b) (6), (b) (7)(C) He was out of state and unable to accompany me on the inspection. He informed me that the seeds had arrived in double wrapped containers that were locked in his storage shed until used. Any remaining seed and the shipping containers were incinerated. He faxed site specific protocols and directions to the site. I was unaccompanied on the inspection but met [REDACTED] (b) (6), (b) (7)(C), (b) (4) at the site.

The 4 test plots covered approximately 5 acres in an L shape. Each plot was marked with metal posts, irrigated and buffered by 10 meters of fallow. No sexually compatible plants were nearby. The plots were surrounded by fallow, barley, and clover. No volunteer wheat or seeds were noted and all vegetation in the buffer areas appeared to have been sprayed with a defoliant. [REDACTED] (b) (6), [REDACTED] (b) (6), [REDACTED] (b) (6) stated that the test plots would be fallowed and monitored for volunteers for 2 years.

On the basis of examination and conversation with [REDACTED] (b) (6), (b) (7)(C) I believe the Performance Standards have been met (please see enclosure).

(b) (6), (b) (7)(C)

Richard J. Merenz
Domestic Program Coordinator, Montana

Enclosure: NOTIFICATION FIELD SITE INSPECTION WORKSHEET

cc: Ralph Stoaks, Regional Program Manager
Gary Adams, State Plant Health Director, Montana
Kimberly Merenz, Quarantine/Nursery Specialist, MDA

Handwritten:
S-I: SW/10/04
6/15/13
JAC

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): 03-022-01 n Crop: Wheat (Nonhybrid)
Applicant's Name: (b) (6), (b) (7)(C) Trait/Gene: Glyphosate tolerant
Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)
Location of Site: (b) (6), (b) (7)(C), (b) (4) MT Date of Inspection: 08/13/03
Type of Location: Farm ☒ Nursery ☐ Research ☐ Other ☐ (Describe) _____
GPS Coordinates (If available): Latitude _____ Longitude _____

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? ☒ Y ☐ N
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? ☒ Y ☐ N

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? ☒ Y ☐ N
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? ☒ Y ☐ N
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- _____ 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? ☐ Y ☐ N
- _____ 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? ☐ Y ☐ N
- _____ 3. Terminating the experiment before flowering.
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? ☐ Y ☐ N
- _____ 4. Physical isolation.
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? ☒ Y ☐ N
- _____ 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? ☐ Y ☐ N

- D. If the applicant's design standards use border rows, are there the state number of border rows? Y N N/A
- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Y N
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y N
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y N
- H. Was the field site marked as stated in the design standards? Y N
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y N
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y N

III. Devitalization.

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y N
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer:

(b) (6), (b) (7)(C)

Phone: (406) 449-5210

Location of PPQ Office

Helena MT

Names and Affiliation of Any Other Persons at the Inspection:

No Other Persons Present

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.



United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine



USDA, APHIS, PPQ
1220 Cole Ave.
Helena, MT 59601
(406) 449-5210
Fax: 449-5212

Federal Relay Service (Voice/TTY/ASCII/Spanish) 800-877-8339

Subject: Notification Field Site Inspection (# 03-022-01n)

Date: September 4, 2003

To: Juan A. Roman, Chief, Biotechnology Program Operations
USDA APHIS BRS
4700 River Rd. Unit 147, 5B53
Riverdale MD 20737

9/10/03

On 13 August 2003 I conducted a Notification Field Site Inspection at the [redacted] (b) (6), (b) (7)(C), (b) (4)
near [redacted] **Not a FOIA Deletion**

Prior to the inspection I called [redacted] (b) (6), (b) (7)(C) Monsanto Company, 408 Deer Drive, Great Falls MT 59404, [redacted] (b) (6), (b) (7)(C) He was out of state and unable to accompany me on the inspection. He informed me that the test plot of non-hybrid Roundup resistant wheat had been mowed prior to flowering on July 3rd, sprayed with Gramexane extra and stated that the site was now in a monitoring phase. The seeds had arrived in double wrapped containers that were locked in his storage shed until used. Any remaining seed and the shipping containers were incinerated. He faxed site specific protocols, and directions to the site. I was unaccompanied on the inspection.

The test plot was approximately 2 acres square, marked with metal posts, irrigated and buffered by 10 meters of fallow. No sexually compatible plants were nearby. The surrounding crop was barley and pasture. The site had been mowed. No volunteer wheat or seeds were noted. [redacted] (b) (6), [redacted] stated that the test plot would be fallowed and monitored for volunteers for 2 years.

On the basis of examination and conversation with [redacted] (b) (6), (b) (7)(C) I believe the Performance Standards have been met (please see enclosure).

[redacted] (b) (6), (b) (7)(C)

Kimberly Merenz
Domestic Program Coordinator, Montana

Enclosure: NOTIFICATION FIELD SITE INSPECTION WORKSHEET

cc: Ralph Stoaks, Regional Program Manager
Gary Adams, State Plant Health Director, Montana
Kimberly Merenz, Quarantine/Nursery Specialist, MDA

9-15-03
del

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): 03-022-01N

Crop: Wheat (Nonhybrid)

Applicant's Name: (b) (6), (b) (7)(C)

Trait/Gene: Glyphosate tolerant

Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4)

Location of Site: (b) (6), (b) (7)(C), (b) (4) MT

Date of Inspection: 08/13/03

Type of Location: Farm ☒ Nursery ☐ Research ☐ Other ☐ (Describe) _____

GPS Coordinates (If available): Latitude _____ Longitude _____

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? (Y) N
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? (Y) N

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? (Y) N
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? (Y) N
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- _____ 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N
- _____ 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? Y N
- _____ 3. Terminating the experiment before flowering.
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N
- _____ 4. Physical isolation.
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? (Y) N
- _____ 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N

D. If the applicant's design standards use border rows, are there the state number of border rows?

Y

N

NA

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species?

Y

N

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards?

Y

N

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards?

Y

N

H. Was the field site marked as stated in the design standards?

Y

N

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts?

Y

N

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive?

Y

N

III. Devitalization.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)?

Y

N

B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer:

(b) (6), (b) (7)(C)

Phone:

(404) 449-5210

Location of PPQ Office

Helena MT

Names and Affiliation of Any Other Persons at the Inspection:

No other Persons Present.

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.

CONFIDENTIAL

2003 Wheat Field Test Report

USDA #03-022-01n

Monsanto #2003-23XRAB

Not A FOIA Deletion

April 23, 2004

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307561	Gallatin	MT	
2147317252	Cascade	MT	
2147314639	Pondera	MT	
2147314638	Judith Basin	MT	
7697	Yellowstone	MT	
2147317253	Cascade	MT	Not Planted

Gallatin County/MT (2147307561)

(b) (4)

8-1: Dwy
4/15/13
Jell
an
4/26/04

(b) (4)

Cascade County/MT (2147317252)

(b) (4)

(b) (4)

Pondera County/MT (2147314639)

(b) (4)

(b) (4)

Judith Basin County/MT (2147314638)

(b) (4)

(b) (4)



CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-022-01n Monsanto #2003-23XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307561	Gallatin	MT	
2147317252	Cascade	MT	
2147314639	Pondera	MT	
2147314638	Judith Basin	MT	
7697	Yellowstone	MT	
2147317253	Cascade	MT	Not Planted

Gallatin County/MT (2147307561)

Planting Date: 04/11/2003

Harvest Date: 08/20/2003

Destruct Date: 08/21/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cascade County/MT (2147317252)

*S. Fieldwork
4/12/13
lee*

Planting Date: 04/24/2003

Destruct Date: 07/10/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Pondera County/MT (2147314639)

Planting Date: 04/28/2003

Harvest Date: 08/30/2003

Destruct Date: 09/03/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Judith Basin County/MT (2147314638)

Planting Date: 05/14/2003

Harvest Date: 08/22/2003

Destruct Date: 08/22/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Yellowstone County/MT (7697)

Planting Date: 04/09/2003

Harvest Date: 08/07/2003

Destruct Date: 08/20/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

1/28/03 11:38 am

Notification Tracking Sheet

=====
Bp number: 03-023-13n
=====

App number: 2003-106XRAB
Received: 1/23/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/22/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/20/03
End movement: 2/20/04
Begin release: 2/20/03
End release: 2/20/04
Acre: 5.00
CBI status: CBI

=====
Fax: 636-737-7085
=====

- | | Initial | Date |
|------------------------------------------------|----------|--------------|
| 1. [✓] Assign Bp number and initial data entry | [ayd] | [1/29/03] |
| 2. [✓] Review by biotechnologist | [gmc]* | [1/29/03]* |
| 3. [✓] Letter of notification to State Fed-ex | [KLn] | [1/30/03]* |
| 4. [] State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Release	* *ID	*	1*WR *

- | | | |
|-------------------------------------------------------------------------------------------------------------------------------------|---------|-------------|
| 5. [✓] Enter genes into database | [ayd] | [1/29/03] |
| 6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw | [KLn] | [2/3/03]* |
| 7. [✓] Enter final data into database | [KLn] | [2/4/03] |
| 8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>**Monsanto Reference ID**
2003-106XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-023-13n

1. USDA Reference Number**2. Application Reference Number** 2003-106XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant**Cultivar(s)/Variety(ies):** Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-106XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2003-106XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 lbs Ship up to _1000_pounds wheat seed to and from each location.

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From/Ship To:

ID

* (b) (4)
(b) (4) Bingham County/Province, ID, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

CONFIDENTIAL

Monsanto Reference ID
2003-106XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)

ID

(b) (4)
(b) (4) Bingham County/Province, ID, (b) (4) U.S.A., 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

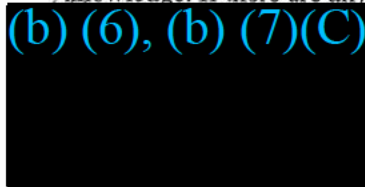
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-106XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 21, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

*CBI-DELETED***MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-106XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-023-13n

1. USDA Reference Number

2. Application Reference Number 2003-106XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

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636/737-7085

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(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-106XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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CBI-DELETED

Monsanto Reference ID
2003-106XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 lbs Ship up to _1000_pounds wheat seed to and from each location.

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From/Ship To:

ID

[CBI Deleted] -- *Bingham County/Province, ID, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID
2003-106XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)

ID

[CBI Deleted] -- Bingham County/Province, ID, U.S.A., 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

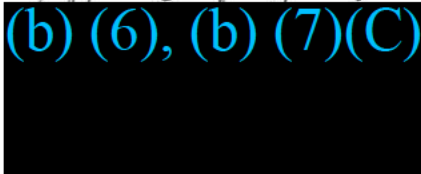
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-106XRAB

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I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 21, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-106XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

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03-023-13n

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Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

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CBI-DELETED

Monsanto Reference ID
2003-106XRAB

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CBI

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CBI-DELETED

Monsanto Reference ID
2003-106XRAB

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PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 lbs Ship up to _1000_pounds wheat seed to and from each location.

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From/Ship To:

ID

[CBI Deleted] -- *Bingham County/Province, ID, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID
2003-106XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)

ID

[CBI Deleted] -- Bingham County/Province, ID, U.S.A., 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-106XRAB

9. Certification

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(b) (6), (b) (7)(C)

Monsanto Company

January 21, 2003

file copy

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 28, 2003

Dear Mr. Cooper:


Enclosed is notification 03-023-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-13n	Applicant #:	2003-106XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010300

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 28, 2003

Dear Mr. Brown:

Enclosed is notification 03-023-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-13n	Applicant #:	2003-106XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010301



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael E. Cooper, Chief
Bureau of Feeds & Plant Services
Idaho State Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

RECEIVED

January 28, 2003

JAN 31 2003

PLANT INDUSTRIES

Dear Mr. Cooper:

Enclosed is notification 03-023-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-13n	Applicant #:	2003-106XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

~~Signature~~

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Cooper

Signature: (b) (6), (b) (7)(C)

Date: 2/2/03

State: Idaho

Rptloc01/R4



February 3, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 22, 2003.

Interstate movement and Release
Notification no. 03-023-13n (2003-106XRAB)
Regulated article - Wheat
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Cooper. Idaho State Dept. of Agric., Boise, ID
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
File number 03-023-13n

OR120018_BR_010303

Confirmation Report-Memory Send

Time : Feb-03-03 04:11pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 293
Date : Feb-03 04:09pm
To : 916367377085
Document Pages : 01
Start time : Feb-03 04:09pm
End time : Feb-03 04:11pm
Pages sent : 01
Job number : 293

*** SEND SUCCESSFUL ***



Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 3, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 22, 2003.

Interstate movement and Release
Notification no. 03-023-13n (2003-106)GRAB)
Regulated article - Wheat
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Cooper, Idaho State Dept. of Agric., Boise, ID
M. Brown, Missouri Dept. of Agric., Jefferson City, MO

OR120018_BR_010304

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-023-13n **Monsanto #2003-106XRAB**

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147302665	Bingham	ID

Bingham County/ID (2147302665)

(b) (4)

apl
4/26/04

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-023-13n Monsanto #2003-106XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147302665	Bingham	ID

Bingham County/ID (2147302665)

Planting Date: 05/12/2003

Harvest Date: 09/24/2003

Destruct Date: 10/03/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/28/03 11:38 am

Notification Tracking Sheet

=====

Bp number: 03-023-14n

=====

App number: 2003-107XRAB
Received: 1/23/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/22/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/20/03
End movement: 2/20/04
Begin release: 2/20/03
End release: 2/20/04
Acre: 20.00
CBI status: CBI
Fax: 636-737-7085

=====

- | | Initial | Date |
|--------------------------------------------------------------------------------------|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [1/29/03] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>gmc</i>]* | [1/29/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KZL</i>] | [1/30/03]* |
| 4. [] State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest	*MN	*	*NER *
Interstate	*Dest	*MO	*	*SCR *
Interstate	*Orig	*MN	*	*NER *
Interstate	*Orig	*MO	*	*SCR *
Release	*	*MN	*	4*NER *

- | | | |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [1/29/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KZL</i>] | [3/12/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KZL</i>] | [3/14/03] |
| 8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

OR120018_BR_010310

**CONFIDENTIAL****MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-107XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-023-14n

1. USDA Reference Number

2. Application Reference Number 2003-107XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-107XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2003-107XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 Ship up to 2000 pounds wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From/Ship To:

MN

* [REDACTED] (b) (4) Polk
County/Province, MN, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] (b) (4), (b) (6), (b) (7)(C) MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

* [REDACTED] (b) (4) County/Province,
MN (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

* [REDACTED] (b) (4)
Dakota County/Province, MN (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] -CBI

* [REDACTED] (b) (4) Stevens County/Province, MN,
(b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
2003-107XRAB

MN, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-107XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4)

MN

(b) (4) Polk County/Province,
MN (b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Ramsey County/Province, MN,
(b) (4) U.S.A., 5 acres (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4)
Dakota County/Province, MN, (b) (4) U.S.A., 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

J-CBI

(b) (4) Stevens County/Province, MN,
(b) (4) USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

J-CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

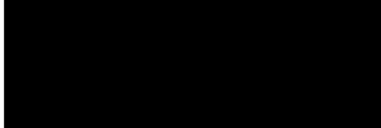
Monsanto Reference ID

2003-107XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 21, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C. Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-107XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 03-023-14n

2. Application Reference Number 2003-107XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-107XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-107XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 Ship up to _2000__pounds wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From/Ship To:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID
2003-107XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 5 acres.

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 5 acres.

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 5 acres.

[CBI Deleted] -- Stevens County/Province, MN, USA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-107XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 21, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-107XRAB

Permit Unit

January 21, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 03-023-14n

2. Application Reference Number 2003-107XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 20, 2003 - February 20, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID

2003-107XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (*Oryza sativa*) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-107XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 Ship up to 2000 pounds wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From/Ship To:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA
[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.
[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.
[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID
2003-107XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 5 acres.

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 5 acres.

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 5 acres.

[CBI Deleted] -- Stevens County/Province, MN, USA, 5 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198


<http://www.monsanto.com>

Monsanto Reference ID
2003-107XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 21, 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 28, 2003

Dear Mr. Brown:

Enclosed is notification 03-023-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-14n	Applicant #:	2003-107XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010330

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 28, 2003

Dear Dr. Hanks:


Enclosed is notification 03-023-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-14n	Applicant #:	2003-107XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010331

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 28, 2003

Dear Mr. Brown:

Enclosed is notification 03-023-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-023-14n	Applicant #:	2003-107XRAB
Received:	January 23, 2003	Effective:	February 22, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010332



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

faxed 3-10-03

January 28, 2003

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

Dear Dr. Hanks:

Enclosed is notification 03-023-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 03-023-14n
Received: January 23, 2003
Institution: Monsanto
Interstate destination: MN MO
Release destination: MN

Applicant #: 2003-107XRAB
Effective: February 22, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached additional conditions.*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *3-10-03*

State: *MN*

Rptloc01/R4



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MAR 10 2003

OR120018_BR_010333

March 12, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 12, 2003.

Interstate movement and Release
Notification no. 03-023-14n (2003-107XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concurs with APHIS determination with the (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
File number 03-023-14n

OR120018_BR_010334



Minnesota Department of Agriculture

(651) 296-1277

March 10, 2003

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 03-023-14n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
 - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains) should not be grown within the field trial area nor within a 33 foot isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 foot isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2003.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hawks, Ph.D.
State Biotechnologist

Confirmation Report-Memory Send

Time : Mar-14-03 01:17pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 831
Date : Mar-14 01:16pm
To : 916367377085
Document Pages : 02
Start time : Mar-14 01:16pm
End time : Mar-14 01:17pm
Pages sent : 02
Job number : 831

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 12, 2003

(b) (6), (b) (7)(C)

Monstante Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 12, 2003.

Interstate movement and Release
Notification no. 03-023-14n (2003-107)RAB)
Regulated article - wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concurs with APHIS determination with the (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010336

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-023-14n **Monsanto #2003-107XRAB**

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303429	Polk	MN	
424036936	Ramsey	MN	
8025	Dakota	MN	Not Planted
2147308819	Stevens	MN	

Polk County/MN (2147303429)

(b) (4)

apl
4/26/04

(b) (4)

Ramsey County/MN (424036936)

(b) (4)

(b) (4)

Stevens County/MN (2147308819)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-023-14n Monsanto #2003-107XRAB

April 23, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303429	Polk	MN	
424036936	Ramsey	MN	
8025	Dakota	MN	Not Planted
2147308819	Stevens	MN	

Polk County/MN (2147303429)

Planting Date: 05/02/2003

Harvest Date: 08/14/2003

Destruct Date: 09/16/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Ramsey County/MN (424036936)

Planting Date: 04/24/2003

Harvest Date: 08/08/2003

Destruct Date: 08/26/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Stevens County/MN (2147308819)

Planting Date: 04/25/2003

Harvest Date: 08/07/2003

Destruct Date: 09/12/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

APHIS Notification Number(s): 03-023-14nCrop: Wheat, Triticum aestivumApplicant's Name: MonsantoTrait/Gene: HTName of Cooperator at Inspected Site: (b) (4), (b) (6), (b) (7)(C)Phone: (b) (4), (b) (6), (b) (7)(C)Location of Site: (b) (4), (b) (6), (b) (7)(C)Date of Inspection: 7/16/03Type of Location: Farm ☐ Nursery ☐ Research ☒ Other ☐ (Describe) _____

GPS Coordinates (If available): Latitude _____ Longitude _____

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

- A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? (Y) N
- B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? (Y) N

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

- A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? NA - whole field treated as transgenic Y N
- B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? (Y) N
- C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.
- _____ 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N
- _____ 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? Y N
- _____ 3. Terminating the experiment before flowering.
C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N
- X 4. Physical isolation.
C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? (Y) N
- _____ 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N
- D. If the applicant's design standards use border rows, are there the state number of border rows? NA Y N

- E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? All Treated as Transgenic NA Y N
- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? NA not grown Y N
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? (Y) N
- H. Was the field site marked as stated in the design standards? (Y) N
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? (Y) N
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Burial. Site monitored for volunteers (Y) N

III. Devitalization.

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? (Y) N
- B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: Scott Smith Phone: 612 725-1771

Location of PPQ Office HHH Int'l, Minneapolis MN

Names and Affiliation of Any Other Persons at the Inspection:

(b) (4), (b) (6), (b) (7)(C)

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Plant Protection
and Quarantine

7150 Humphrey Drive
Suite 2189
Minneapolis MN 55450

Phone: (612) 725-1771
Fax: (612) 725-1741

July 23, 2003

W. Scott Wood
USDA, APHIS, PPQ
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Mr. Wood,

On July 16, 2003 I inspected field release notification site 03-023-14n. (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) accompanied me during the inspection.

As indicated on the enclosed sheet, there were no problems with the field currently.

Most of the wheat will be harvested by combine. The combine will be cleaned with a vacuum in the field. The harvested material will be brought back to a laboratory for final cleaning. A subsample of this wheat will be sent to Monsanto. The rest will be buried in the field with the plant waste that came from the original combining.

Certain rows of the wheat will be hand harvested but cutting heads off and placing the heads in envelopes. The resulting seeds will be kept in this lab for about a month, and then sent elsewhere for replanting. (b) (4), (b) (6), (b) (7)(C) was not sure exactly where although he mentioned MN or HI as possibilities.

Please let me know if you need further information regarding this site.

Thank you,

Scott Smith



APHIS Protecting American Agriculture

Equal Opportunity Employer

OR120018_BR_010348

2/25/03 8:56 am

Notification Tracking Sheet

=====
Bp number: 03-052-24n
=====

App number: 2003-200XRAB
Received: 2/21/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/23/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085
=====

- | | Initial | Date |
|--------------------------------------------------------------------------------|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/25/03] |
| 2. <input type="checkbox"/> Review by biotechnologist | [j/m]* | [2/25/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [Kolo] | [2/27/03]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate *Dest*MO *			*SCR *
Interstate *Dest*SD *			*SCR *
Interstate *Orig*MO *			*SCR *
Interstate *Orig*SD *			*SCR *
Release * *SD *			2*SCR *

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/25/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw | [Kolo] | [3/4/03]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [Kolo] | [3/6/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-200XRAB

Permit Unit

February 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-24n

1. USDA Reference Number

2. Application Reference Number 2003-200XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 14, 2003 - March 14, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-200XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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CONFIDENTIAL

Monsanto Reference ID
2003-200XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 lbs Ship up to 2000 pounds wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From/Ship To:

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA

] - CBI

SD

* (b) (4), (b) (6), (b) (7)(C) Brookings County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4), (b) (6), (b) (7)(C) Codington County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Brookings
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
2003-200XRAB

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-200XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

(b) (4), (b) (6), (b) (7)(C) Brookings County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA, 5 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Codington County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

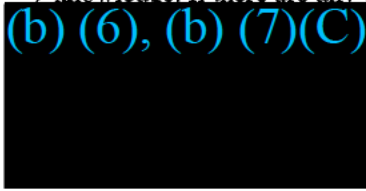
<http://www.monsanto.com>

Monsanto Reference ID
2003-200XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 12, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-200XRAB

Permit Unit

February 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-24n

1. USDA Reference Number

2. Application Reference Number 2003-200XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 14, 2003 - March 14, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID

2003-200XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

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CBI-DELETED

Monsanto Reference ID
2003-200XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 lbs Ship up to 2000 pounds wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-200XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 5 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres.

MONSANTO



CBI-DELETED

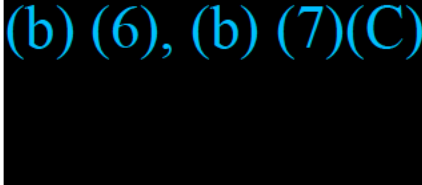
Monsanto Reference ID
2003-200XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

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(b) (6), (b) (7)(C)



Monsanto Company

February 12, 2003

MONSANTO



CBI-DELETED

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Email

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2003-200XRAB

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CBI

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CBI-DELETED

Monsanto Reference ID
2003-200XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4 ;	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 lbs Ship up to _2000__pounds wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2003-200XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 5 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres.

MONSANTO



CBI-DELETED

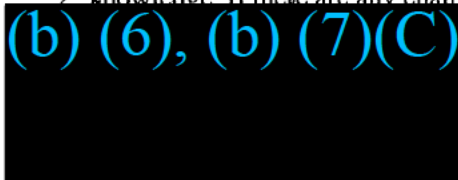
Monsanto Reference ID
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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
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<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 12, 2003

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-24n	Applicant #:	2003-200XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010369

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 25, 2003

Dear Mr. Fridley:

Enclosed is notification 03-052-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-24n	Applicant #:	2003-200XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010370



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-24n	Applicant #:	2003-200XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 25, 2003

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 03-052-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number: 03-052-24n
Received: February 21, 2003
Institution: Monsanto
Interstate destination: MO SD
Release destination: SD

Applicant #: 2003-200XRAB
Effective: March 23, 2003
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/28/03

State: South Dakota

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010372

MAR 3 2003

March 4, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway W.
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2003.

Interstate movement and Release
Notification no. 03-052-24n (2003-200XRAB)
Regulated article - Wheat
Destinations - Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept of. Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 03-052-24n

OR120018_BR_010373

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

AHPIS Notification Number: 03 052 24n

Applicant's Name: (b) (6), (b) (7)(C)

Name of Cooperator at inspection site: (b) (6), (b) (7)(C), (b) (4)

Location of site: Brookings Co.

Type of location: Farm ☒ Nursery ☐ Other ☐ (describe) _____

GPS/ GIS Coordinates (if available): Latitude _____

Crop: wheat

Trait/Gene: HT-glyphosate

Phone: (b) (6), (b) (7)(C), (b) (4)

Date of Inspection: 7-16-03

Longitude _____

7/23/03

Provide the answers below. Check "Y" for Yes and "N" for No. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identity (seed storage, planting & harvest site, borders, field cages, etc.)? triple containerized

Y ☒ N ☐

B. Was a site map obtained or drawn by your for reference later (For harvest, flower removal, volunteers, etc.)?

Y ☒ N ☐

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop?

no cultivated plantings

Y ☒ N ☐

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants?

no compatible species

Y ☒ N ☐

C. Which of the five containment options is the applicant using? Check one of the options below. If none, please not it here and state this in your cover letter to the Regional Program Manager. _____

1. Removing Flowers _____

Is there any evidence that the plants have flowers or that flowers have been removed?

Y ☐ N ☐

2. Bagging Flowers/Tassels _____

Does the applicant have material to bag reproductive structures?

Y ☐ N ☐

3. Terminating the experiment before flowering _____

Were plants destroyed or removed from the field before any flowers were allowed to release pollen?

Y ☐ N ☐

4. Physical Isolation X

If there are any non-transgenic compatible plants within the distance stated in Table 1 (for pollination distance), were they being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics?

- no cultivated plantings within several miles of site

Y ☐ N ☐

5. Temporal Isolation _____

Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap?

Y ☐ N ☐

D. If the applicant's design standards use border rows, are there the stated number of border rows? no rows required

Y ☒ N ☐

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species?

- alley system present no cultivated plantings nearby

Y ☒ N ☐

Revised 7/2/03

OR120018_BR_010374

- F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? *no transgenic previous year* Y ☐ N ☐
- G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? *monthly monitoring* Y ☒ N ☐
- H. Was the field site marked as stated in the design standards? *corner flags missing* Y ☒ N ☐
- I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? *dedicated machinery cleaned on site* Y ☒ N ☐
- J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y ☒ N ☐

III. Devitalization

- A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y ☒ N ☐
- B. Remind applicant that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed and approved.

Inspecting Officer Signature:

(b) (6), (b) (7)(C)

Printed Name:

Amy Mesman

Phone:

605 224-1713

Location of PPQ Officer:

Pierre SD 57501

Names and Affiliation of Any Other Persons at the inspection:

(b) (6), (b) (7)(C), (b) (4)

Monsanto

Please fax or email completed worksheet to:
Ralph Stoaks, Regional Biotechnologist
2150 Centre Ave. Bldg. B, 3E10
Ft. Collins, CO 80526
Phone: 970-494-7573
Fax: 970-494-7576
Email: ralph.d.stoaks@aphis.usda.gov

- 100lbs of seed received
- Site was non-gmo corn in 2002
will be non gmo corn in 2003

Please FedEx original worksheet to:
Tony Roman, Chief Biotechnology Program Operations
4700 River Road, Unit 147, 5B53
Riverdale, MD 20737
Phone: 301-734-0029

Revised 7/2/03

OR120018_BR_010375

(b) (4)



CONFIDENTIAL

2003 Wheat Field Test Report

USDA [REDACTED]

Monsanto #2003-200XRAB

Not a FOIA Deletion

February 17, 2004

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147317546	Brookings	SD
2147317547	Codington	SD

Brookings County/SD (2147317546)

(b) (4)

ad
2/18/04

(b) (4)

Codington County/SD (2147317547)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-052-24n Monsanto #2003-200XRAB

February 17, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147317546	Brookings	SD
2147317547	Codington	SD

Brookings County/SD (2147317546)

Planting Date: 04/29/2003

Harvest Date: 08/12/2003

Destruct Date: 08/13/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Codington County/SD (2147317547)

Planting Date: 05/01/2003

Harvest Date: 08/12/2003

Destruct Date: 08/13/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

=====

Bp number: 03-052-27n

=====

App number: 2003-205XRAB
 Received: 2/21/03
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/23/03
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

- | | Initial | Date |
|--------------------------------------------------------------------------------------|----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [2/25/03] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>VM</i>]* | [2/25/03]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>Kal</i>] | [2/27/03]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	ND	*	*SCR	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	ND	*	*SCR	*
Release	*	*ND	*	3*SCR	*

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [2/25/03] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw | [<i>Kal</i>] | [3/21/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>Kal</i>] | [3/24/03] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

**CONFIDENTIAL**

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>**Monsanto Reference ID**
2003-205XRAB

Permit Unit

February 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-27n

1. USDA Reference Number**2. Application Reference Number** 2003-205XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 14, 2003 - March 14, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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Monsanto Reference ID
2003-205XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2003-205XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/12	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 lbs Ship up to _2000_ pounds wheat seed to and from each location.

ORIGIN:

MO, ND

DESTINATION:

MO, ND

Ship From/Ship To:

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA

] -CBI

ND

* (b) (4) Cass County/Province, ND, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) PO
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Foster County/Province,
ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

* (b) (4) Cavalier
County/Province, ND, (b) (4) USA

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Monsanto Reference ID
2003-205XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) PO
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-205XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[(b) (4)] Cass County/Province, ND [(b) (4)] USA, 6
acres. [(b) (4)]

RESPONSIBLE PERSON/RESEARCHER: [(b) (4), (b) (6), (b) (7)(C)]
[(b) (4), (b) (6), (b) (7)(C)] ND, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

[(b) (4)] Foster County/Province, ND,
[(b) (4)] U.S.A., 5 acres [(b) (4)]

RESPONSIBLE PERSON/RESEARCHER: [(b) (4), (b) (6), (b) (7)(C)]
[(b) (4), (b) (6), (b) (7)(C)] ND, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

[(b) (4)] Cavalier
County/Province, ND [(b) (4)] USA, 5 acres. [(b) (4)]

RESPONSIBLE PERSON/RESEARCHER: [(b) (4), (b) (6), (b) (7)(C)]
[(b) (4), (b) (6), (b) (7)(C)] ND, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-205XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 12, 2003

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-205XRAB

Permit Unit

February 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-27n

1. USDA Reference Number**2. Application Reference Number** 2003-205XRAB**3. Application/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 14, 2003 - March 14, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article**Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-205XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-205XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 lbs Ship up to _2000_pounds wheat seed to and from each location.

ORIGIN:

MO, ND

DESTINATION:

MO, ND

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Cavalier County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2003-205XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 6 acres.

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 5 acres.

[CBI Deleted] -- Cavalier County/Province, ND, USA, 5 acres.

MONSANTO



CBI-DELETED

Monsanto Reference ID
2003-205XRAB

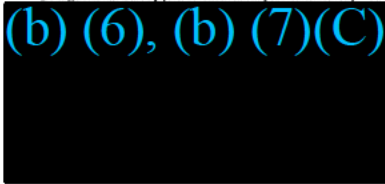
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 12, 2003

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

Monsanto Reference ID
2003-205XRAB

Permit Unit

February 12, 2003

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-27n

1. USDA Reference Number

2. Application Reference Number 2003-205XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 14, 2003 - March 14, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID

2003-205XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

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CBI-DELETED

Monsanto Reference ID

2003-205XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4 ;	NOS 3'	Disarmed Agrobacterium tumefaciens
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8. Introduction Interstate Movement and Release

2000 lbs Ship up to _2000_pounds wheat seed to and from each location.

ORIGIN:

MO, ND

DESTINATION:

MO, ND

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Cavalier County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2003-205XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 6 acres.

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 5 acres.

[CBI Deleted] -- Cavalier County/Province, ND, USA, 5 acres.

MONSANTO



CBI-DELETED

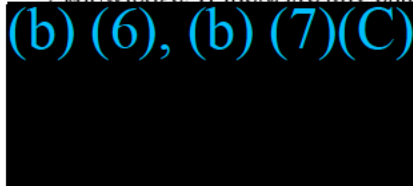
Monsanto Reference ID
2003-205XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 12, 2003



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-27n	Applicant #:	2003-205XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010405

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-27n	Applicant #:	2003-205XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010406

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 25, 2003

Dear Mr. Nelson:

Enclosed is notification 03-052-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-27n	Applicant #:	2003-205XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010407



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 25, 2003

Dear Mr. Nelson:

Enclosed is notification 03-052-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	03-052-27n	Applicant #:	2003-205XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. *to Supplemental Conditions letter, as March 12, 2003*

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *David R. Nelson*

Signature: (b) (6), (b) (7)(C)

Date: *3/12/03*

State: *ND*

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_010408

MAR 12 2003

March 21, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 21, 2003.

Interstate movement and Release
Notification no. 03-052-27n (2003-205XRAB)
Regulated article - Wheat
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (letter attached dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,



Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 03-052-27n

OR120018_BR_010409

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson

DATE: March 12, 2003

RE: Supplemental Conditions for Release of Wheat
Bp 03-015-10n
Bp 03-052-27n
Bp 03-052-59n
Bp 03-059-05n

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2003

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

OR120018_BR_010410

Confirmation Report-Memory Send

Time : Mar-24-03 09:19am
Tel line 1 :
Tel line 2 :
Name :

Job number : 010
Date : Mar-24 09:17am
To : 916367377085
Document Pages : 02
Start time : Mar-24 09:17am
End time : Mar-24 09:19am
Pages sent : 02
Job number : 010

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 21, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear Ms. Hunter:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 21, 2003.

Interstate movement and Release
Notification no. 03-052-27n (2003-205XRAB)
Regulated article - Wheat
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota concurs with APHIS determination, with supplemental conditions (letter attached dated March 12, 2003).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010411

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-052-27n **Monsanto #2003-205XRAB**

April 7, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317549	Cass	ND	
1611677957	Foster	ND	Not Planted
2147320702	Cavalier	ND	

Cass County/ND (2147317549)

(b) (4)

apb
4/8/04

(b) (4)

Cavalier County/ND (2147320702)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-052-27n Monsanto #2003-205XRAB

April 7, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147317549	Cass	ND	
1611677957	Foster	ND	Not Planted
2147320702	Cavalier	ND	

Cass County/ND (2147317549)

Planting Date: 05/31/2003

Harvest Date: 08/28/2003

Destruct Date: 08/28/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cavalier County/ND (2147320702)

Planting Date: 05/12/2003

Harvest Date: 08/26/2003

Destruct Date: 08/27/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

8/8/03

PERMIT NUMBER 03-052-27N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)

LOCATION (b) (4) PHONE (b) (4)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF
RELEASE May 12/03

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO _____
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? Flax YES ☒ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO _____
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO _____
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO _____
7. WHAT WAS ON EACH SIDE OF THE PLOT?

(b) (4) NORTH Barley
SOUTH Barley
EAST Canola
WEST Barley

8. BORDER BUFFER AREA REQUIRED? 33 Black YES ☒ NO _____

330' from wheat HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO _____

10. WAS SEED STORAGE AREA INSPECTED? Brought seed with him YES ☒ NO _____

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO _____

LABELLED? YES ☒ NO _____

12. NUMBER OF REGULATED ARTICLES RELEASED 1/2 Acre
NUMBER OF TRANSGENIC LINES IN TEST _____

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left - Buried envelopes in field

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned in field

INSPECTING PPQ OFFICER (b) (6), (b) (7)(C)
Wendal Beshing PHONE (701) 228-2825
LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010419

(b) (4)

(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEETPERMIT NUMBER 03-052-23N CROP wheatORGANIZATION / COMPANY MonsantoRESPONSIBLE APPLICANT (b) (4), (b) (6), (b) (7)(C)COOPERATOR CONTACT PERSON (b) (4), (b) (6), (b) (7)(C)LOCATION (b) (4), (b) (6), (b) (7)(C) PHONE (b) (4), (b) (6), (b) (7)(C)TYPE OF LOCATION: Farm Nursery ☒ Research General OtherDATE PPQ NOTIFIED OF FIELD RELEASE may 31/03 ACTUAL DATE OF
RELEASE may 31/03DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO ☐2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES ☐ NO ☐3. NUMBER OF VOLUNTEERS CROP PERMIT NUMBER4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO ☐5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO ☐6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO ☐

7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH wheatSOUTH wheatEAST wheatWEST Boylemans8. BORDER BUFFER AREA REQUIRED? 330' from other wheat YES ☒ NO ☐9. WERE SPECIAL PERMIT CONDITIONS MET? 331 Border HOW MUCH? YES ☒ NO ☐10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO ☐11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO ☐* 12. NUMBER OF REGULATED ARTICLES RELEASED PLANTED 44.7 Lbs LABELLED? YES ☒ NO ☐13. NUMBER OF TRANSGENIC LINES IN TEST 410 ENTRIES

14. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS PLACED IN LOCKED STORAGE

15. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? COMPRESSED AIR
(EQUIPMENT USED ARE EXCLUSIVE TO REGULATED WHEAT)INSPECTING PPQ OFFICER (b) (6), (b) (7)(C)LOCATION OF PPQ OFFICE (b) (4), (b) (6), (b) (7)(C) PHONE (701) 228-2825OTHER PERSONS AT INSPECTION (b) (4), (b) (6), (b) (7)(C)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

* Called Wmde and asked him: (Lbs planted) (06/18/03)

OR120018_BR_010421

(b) (4)

w)

(b) (4)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-052-27N CROP wheat
ORGANIZATION /COMPANY Moments (b) (4), (b) (6), (b) (7)(C)
LOCATION (b) (4) North Dakota
DATE OF PPQ NOTIFIED OF HARVEST 8/25/03 ACTUAL HARVEST DATE 8/26/03
DATE OF HARVEST INSPECTION 8/26/03
HOW WAS CROP TERMINATED? Harvested by Combine
DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
all plant material will be incorporated into the soil in the plot area.
HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Vacuum cleaner and compressed air
WERE REGULATED ARTICLES SHIPPED OUT OF STATE? WHERE?
PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes
DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes
DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS?
INSPECTING PPQ OFFICER Wendal & Cushing PHONE (701) 228-2825
LOCATION OF PPQ OFFICE Bohndale, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager People Present at Harvest
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

1 (b) (4), (b) (6), (b) (7)(C)
2
3
4

9/1/03

(b) (4), (b) (6), (b) (7)(C)



(b) (4)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-052-27N CROP wheat
 ORGANIZATION /COMPANY monsanto (b) (4), (b) (6), (b) (7)(C)
 LOCATION (b) (4) North Dakota
 DATE OF PPQ NOTIFIED OF HARVEST 8/27/03 ACTUAL HARVEST DATE 8/28/03
 DATE OF HARVEST INSPECTION 8/28/03
 HOW WAS CROP TERMINATED? Harvested
 DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
harvested, seed was cleaned in the plot area, seed was then bagged and placed in locked boxes and taken back to the university and locked in the storage area.
debris worked into plot area immediately after harvest
 HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned by vacuum and air pressure
 WERE REGULATED ARTICLES SHIPPED OUT OF STATE? Not yet, but will be shipped to Colorado and St. Louis WHERE? yes
 PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE Compliance form - 03-112-117
 DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes - next year
 DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendal Q. Cushing PHONE (701) 228-²⁸²⁵~~3826~~
 LOCATION OF PPQ OFFICE Bottineau, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
 USDA, APHIS, PPQ
 9580 Micron Avenue, Suite 1
 Sacramento, CA 95827
 Phone: (916) 857-6105
 FAX: (916) 857-6100

Others present at Harvest

1. (b) (4), (b) (6), (b) (7)(C)
 2.
 3.
 4.

(b) (4), (b) (6), (b) (7)(C)



Wheat

*Label placed on
Seed boxes for transit.*

USDA# 03- 052-27n

Monsanto # 2003-205XRAB

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY WEST

CHESTERFIELD, MISSOURI 63017

<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

The new name/address information is:

(b) (4)

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010428

MONSANTO



CBI - DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:
[CBI DELETED] - Cavalier, ND

The new name/address information is:
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010429

(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

8/5/03

PERMIT NUMBER 03-052-27N CROP Wheat

ORGANIZATION / COMPANY Monsanto

RESPONSIBLE APPLICANT _____

COOPERATOR CONTACT PERSON (b) (6), (b) (7)(C), (b) (4)

LOCATION (b) (4) PHONE () (b) (4)

TYPE OF LOCATION: Farm Nursery ☒ Research General Other

DATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF

RELEASE May 12/03

DATE OF FIELD INSPECTION 6/9/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO
2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? Flax YES ☒ NO ☒
3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO
7. WHAT WAS ON EACH SIDE OF THE PLOT?

(b) (4) NORTH Barley
SOUTH Barley
EAST Conola
WEST Barley

8. BORDER BUFFER AREA REQUIRED? 33 Black YES ☒ NO

330' from wheat HOW MUCH? _____

9. WERE SPECIAL PERMIT CONDITIONS MET? YES ☒ NO

10. WAS SEED STORAGE AREA INSPECTED? Brought seed with him YES ☒ NO

11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO

LABELLED? YES ☒ NO

12. NUMBER OF REGULATED ARTICLES RELEASED 1/2 Acre

NUMBER OF TRANSGENIC LINES IN TEST _____

13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS None left - Buried envelope in field

14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? _____

Cleaned in field

INSPECTING PPQ OFFICER (b) (6), (b) (7)(C) PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (6), (b) (7)(C), (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO : DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST

USDA, APHIS, PPQ

PHONE: 573-893-6833

OR120018_BR_010430

(b) (6), (b) (7)(C), (b) (4)



(b) (4)

CENTRAL REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

EW
8/18/03

PERMIT NUMBER 03-053-23N CROP wheatORGANIZATION / COMPANY MonsantoRESPONSIBLE APPLICANT (b) (6), (b) (7)(C), (b) (4)

COOPERATOR CONTACT PERSON _____

LOCATION (b) (6), (b) (7)(C), (b) (4) PHONE (b) (6), (b) (7)(C), (b) (4)TYPE OF LOCATION: Farm Nursery ☒ Research General OtherDATE PPQ NOTIFIED OF FIELD RELEASE _____ ACTUAL DATE OF RELEASE May 31/03DATE OF FIELD INSPECTION 6/17/03

SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES ☒ NO _____
 2. WERE VOLUNTEER PLANTS FOUND FROM PREVIOUS FIELD RELEASE? YES _____ NO _____
 3. NUMBER OF VOLUNTEERS _____ CROP _____ PERMIT NUMBER _____
 4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES ☒ NO _____
 5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES ☒ NO _____
 6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES ☒ NO _____
 7. WHAT WAS ON EACH SIDE OF THE PLOT?

NORTH wheat
 SOUTH wheat
 EAST wheat
 WEST Boyslans

8. BORDER BUFFER AREA REQUIRED? 330' border wheat YES ☒ NO _____9. WERE SPECIAL PERMIT CONDITIONS MET? 331 Border HOW MUCH? YES ☒ NO _____10. WAS SEED STORAGE AREA INSPECTED? YES ☒ NO _____11. WERE SHIPPING CONTAINERS INSPECTED? YES ☒ NO _____* ☒ 12. NUMBER OF REGULATED ARTICLES PLANTED RELEASED 44.7 Lbs LABELLED? YES ☒ NO _____✓ 13. NUMBER OF TRANSGENIC LINES IN TEST 410 ENTRIES✓ 14. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS PLACED IN LOCKED STORAGE✓ 14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? COMPRESSED AIR.
(EQUIPMENT USED ARE EXCLUSIVE TO REGULATED WHEAT)INSPECTING PPQ OFFICER Wendal J. Cushing PHONE (701) 228-2825

LOCATION OF PPQ OFFICE _____

OTHER PERSONS AT INSPECTION (b) (6), (b) (7)(C), (b) (4)

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: DANA E. DEWEESE, REGIONAL BIOTECHNOLOGIST
USDA, APHIS, PPQ

PHONE: 573-893-6833

* Called Wendle and asked him: (Lbs planted) (06/18/03)

OR120018_BR_010432

(b) (6), (b) (7)(C), (b) (4)



w

(b) (6), (b) (7)(C), (b) (4)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-052-27N CROP wheat
ORGANIZATION /COMPANY Monsanto (b) (6), (b) (7)(C)
LOCATION (b) (6), (b) (7)(C), (b) (4) North Dakota
DATE OF PPQ NOTIFIED OF HARVEST 8/25/03 ACTUAL HARVEST DATE 8/26/03
DATE OF HARVEST INSPECTION 8/26/03
HOW WAS CROP TERMINATED? Harvested by Combine
DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)
all plant material will be incorporated into the soil in the plot area.
HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Vacuum cleaners and compressed air
WERE REGULATED ARTICLES SHIPPED OUT OF STATE? WHERE?
PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE
DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes
DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS?

INSPECTING PPQ OFFICER Wendal & Cushing PHONE (701) 228-2825
LOCATION OF PPQ OFFICE Bohndake, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager People present at Harvest
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

1. (b) (6), (b) (7)(C), (b) (4)
2.
3.
4.

9/1/03

(b) (6), (b) (7)(C), (b) (4)



(b) (4)

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER 03-052-27N CROP wheat

ORGANIZATION /COMPANY monsanto (b) (6), (b) (7)(C), (b) (4)

LOCATION (b) (4) North Dakota

DATE OF PPQ NOTIFIED OF HARVEST 8/27/03 ACTUAL HARVEST DATE 8/28/03

DATE OF HARVEST INSPECTION 8/28/03

HOW WAS CROP TERMINATED? Harvested

DESCRIBE METHOD OF DISPOSAL OF REGULATED: (Plant debris, seeds, fruits, tubers, plant parts, etc.)

harvested, seed was cleaned in the plot area, seed was then bagged and placed in locked boxes and taken back to the university and locked in the storage area.

debris worked into plot area immediately after harvest-
HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL? Cleaned by vacuum and air pressure

WERE REGULATED ARTICLES SHIPPED OUT OF STATE? WHERE?

Not yet, but will be shipped to Colorado and St. Louis
PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE yes

Compliance form - 03-112-16m
DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT? yes - next year

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS? yes

INSPECTING PPQ OFFICER Wendal G. Cushing PHONE (201) 228-²⁸²⁵~~3336~~

LOCATION OF PPQ OFFICE Bohannon, N. Dak

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite 1
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

Others Present at Harvest

1. (b) (4), (b) (7)(C), (b) (6)
- 2.
- 3.
- 4.

(b) (4), (b) (6), (b) (7)(C)



Wheat

*lot is placed on
seed boxes for transit.*

USDA# 03- 052-27n

Monsanto # 2003-205XRAB

(b) (4), (b) (6), (b) (7)(C)

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

The new name/address information is:

(b) (4)

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010440

MONSANTO



CBI - DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:
[CBI DELETED] - Cavalier, ND

The new name/address information is:
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018_BR_010441

2/25/03 8:56 am

Notification Tracking Sheet

=====
Bp number: 03-052-28n
=====

App number: 2003-206XRAB
Received: 2/21/03
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/23/03
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 3/15/03
End movement: 3/15/04
Begin release: 3/15/03
End release: 3/15/04
Acre: 22.00
CBI status: CBI
Fax: 636-737-7085
=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>aid</i>]	[2/25/03]
2. <input type="checkbox"/> Review by biotechnologist	[<i>UM</i>]*	[2/25/03]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed ex</i>	[<i>K&L</i>]	[2/27/03]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	MT	*	*WR	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	MT	*	*WR	*
Release	*	*MT	*	4*WR	*

5. <input checked="" type="checkbox"/> Enter genes into database	[<i>aid</i>]	[2/25/03]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw	[<i>K&L</i>]	[3/3/03]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>K&L</i>]	[3/4/03]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-206XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-28n

1. USDA Reference Number

2. Application Reference Number 2003-206XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 15, 2003 - March 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2003-206XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2003-206XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

5000 lbs Ship up to _5000_ pounds wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From/Ship To:

MO

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

MT

* (b) (4) Fergus County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

] -CBI

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

CONFIDENTIAL

Monsanto Reference ID
2003-206XRAB

] -CBI

*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

*[(b) (4)] Park County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

CONFIDENTIAL

Monsanto Reference ID
2003-206XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(4)

MT

(b) (4) Fergus County/Province, MT, (b) (4) USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4) Gallatin County/Province, MT, (b) (4) USA, 6 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

(b) (4), (b) (6), (b) (7)(C) Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA, 8 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] -CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

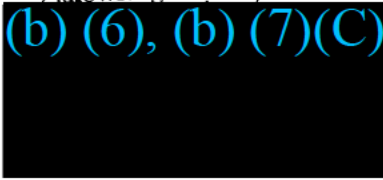
<http://www.monsanto.com>

Monsanto Reference ID
2003-206XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID
2003-206XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-28n

1. USDA Reference Number

2. Application Reference Number 2003-206XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 15, 2003 - March 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

5000 lbs Ship up to _5000__pounds wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Fergus County/Province, MT, USA

[CBI Deleted] -- *Teton County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Park County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(4)

MT

[CBI Deleted] -- Fergus County/Province, MT, USA, 4 acres.

[CBI Deleted] -- Teton County/Province, MT, USA, 4 acres.

[CBI Deleted] -- Gallatin County/Province, MT, USA, 6 acres.

[CBI Deleted] -- Gallatin County/Province, MT, USA, 8 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

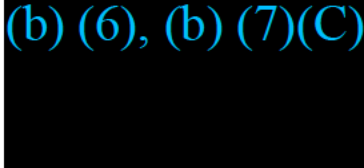
Monsanto Reference ID

2003-206XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Monsanto Reference ID

2003-206XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

03-052-28n

1. USDA Reference Number

2. Application Reference Number 2003-206XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Fax

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release

March 15, 2003 - March 15, 2004

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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GENE OF INTEREST

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Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

5000 lbs Ship up to _5000_ pounds wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Fergus County/Province, MT, USA

[CBI Deleted] -- *Teton County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Park County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2003-206XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(4)

MT

[CBI Deleted] -- Fergus County/Province, MT, USA, 4 acres.

[CBI Deleted] -- Teton County/Province, MT, USA, 4 acres.

[CBI Deleted] -- Gallatin County/Province, MT, USA, 6 acres.

[CBI Deleted] -- Gallatin County/Province, MT, USA, 8 acres.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

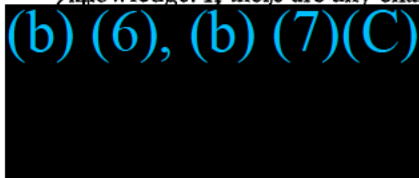
Monsanto Reference ID

2003-206XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

Enclosed is notification 03-052-28n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-28n	Applicant #:	2003-206XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010462

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 25, 2003

Dear Mr. Ames:


Enclosed is notification 03-052-28n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	03-052-28n	Applicant #:	2003-206XRAB
Received:	February 21, 2003	Effective:	March 23, 2003
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Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_010463



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 25, 2003

Dear Mr. Brown:

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Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
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Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 25, 2003

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Received:	February 21, 2003	Effective:	March 23, 2003
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/28/03

State: Montana

Rptloc01/R4



March 3, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway W.
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2003.

Interstate movement and Release
Notification no. 03-052-28n (2003-206XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
File number 03-052-28n

OR120018_BR_010466

Confirmation Report-Memory Send

Time : Mar-03-03 11:40am
Tel line 1 :
Tel line 2 :
Name :

Job number : 624
Date : Mar-03 11:39am
To : 916367377085
Document Pages : 02
Start time : Mar-03 11:39am
End time : Mar-03 11:40am
Pages sent : 02
Job number : 624

*** SEND SUCCESSFUL ***



Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 3, 2003

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway W.
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2003.

Interstate movement and Release
Notification no. 03-052-28n (2003-206XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana

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This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_010467

WESTERN REGION
NOTIFICATION INSPECTION WORKSHEET
regarding 340.3(c)

C
7/18/03

03-052-287

Non Hybrid

BIOTECH NUMBER: 2003-206 X BAB

CROP wheat

DATE PLANTED 4/28/03

APPLICANT

COMPANY Monsanto Company

COOPERATOR CONTACT PERSON

TEL/FAX

SITE LOCATION

(b) (6), (b) (7)(C), (b) (4)

Fergus Co. MT

DATE OF INSPECTION

6/19/03

Inspection Team, (1) PPQO

Kimberly Merenz

Cooperator (2) Applicant

(b) (6), (b) (7)(C), (b) (4)

(3) State

Check one:

☐ Field Release

☐ Harvest

☒ Monitor

SUMMARY OF PERFORMANCE STANDARDS Refer to User's Guide for Submitting Notifications for inspection protocols, i.e., crop isolation distances and outcross prevention.

1. Did viable plant material escape during shipping or at destination? (Ex. Shipping container should be sturdy and have notification number written on outside). Yes ☐ No ☒
2. Separation is maintained between regulated plant material and non regulated plant material to prevent mixing (Note isolation distances and border rows in User's Guide). Yes ☒ No ☐
- 3a. Identity of plant material was maintained while in use? (Plot maps and attention to marked reference points to identify volunteers in spring after test plot is gone). Yes ☒ No ☐

THESE STANDARDS PERTAIN MAINLY TO MATURE PLANTS

- 3b. Plant material is being contained (Ex: all material harvested or devitalization was by burning). Yes ☐ No ☐
4. The researcher/cooperator must advise you if crown gall is present after planting. Was it reported as being present? Yes ☐ No ☐
5. Field trial is being conducted in manner to avert persistence in the environment (controlling pollination, etc.)? Yes ☐ No ☐
6. Upon termination, was material handled to prevent volunteers? Yes ☐ No ☐

INSPECTING PPQ OFFICER

Kimberly D. Merenz

PHONE (406) 449-5210

LOCATION OF PPQ OFFICE

1220 Cole Ave, Helena, MT 59601

Any other pertinent information the inspecting officer can furnish is appreciated.

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

REVISED 01/24/97

OR120018_BR_010468

(b) (4)

(b) (4)

WHEAT FIELD RELEASE

PERFORMANCE STANDARDS

Notification to allow movement of material regulated by the USDA-APHIS must be in place prior to shipment. This includes shipment of the seed (or other plant material) to a site to initiate a field trial as well as shipment of harvested seed (or other plant material) from a field trial site to another location. Harvested commodities from field trials of regulated plant material must not be allowed to enter commerce as a food or feed product.

Shipping

When shipping, all packages must be clearly labeled as to content and the USDA notification number must be prominently displayed on the outer package (for example, USDA #00-000-00n, Wheat).

Regulated plant materials shipped will include any viable plant parts as described in the notification. For most plant material, any shipping container that consists of an inner container that is a sturdy bag, box, or other such structure, enclosed in an outer container that is also a sturdy bag, box, or other such structure is acceptable under most circumstances. Both inner container and outer container must be capable of preventing seed or material loss.

If transfer of the regulated material is to take place within the state and is not noted on the notification, the state regulatory official must be contacted before the movement may occur. The name and the phone number of the state official to contact can be found in the letter immediately after the cover page in the compliance packet.

Maintenance at Destination

When regulated material is received at contained facilities, such as storage rooms or greenhouses, it should be handled and stored in such a way that there is no release into the environment (for example, stored in a locked file or storage cabinet). This requires ensuring that regulated material is not accidentally mixed with non-regulated material, does not transfer genes to non-regulated material inside or outside the facility, and does not accidentally escape from the contained facility.

To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as obvious marks, color-coding, or strict segregation of material should be implemented.

Seed and/or other plant material that will be planted directly in the field should be kept secure until needed for planting. If excess seed and/or plant material exists after planting, this material should be devitalized using suitable means as given in the "Devitalization" section of this document or returned to the contained facility. To minimize pollen-mediated gene flow out of a contained facility, physical barriers or methods such as sterilization or bagging should be used. Similar methods should be used to prevent pollen flow to receptive plants within the contained facility as well.

Persistence in the Environment

To prevent the regulated material in the field trial from persisting in the environment, devitalization treatments given in the "Devitalization" section of this document, should be utilized. To prevent offspring from being formed and persisting, means must be taken to minimize the likelihood of pollination and successful fertilization of receptive plants outside the field trial area.

The following are minimum standards of isolation that will minimize the likelihood of pollination of receptive wheat, durum or triticale plants outside of the field trial area:

- 1) A minimum isolation distance of 33 feet (10 M) must be maintained between the trial and any wheat, durum or triticale planting that will produce seed to be saved for seed production.**

The isolation area from the trial can be:

Wheat Performance Standards (Cont'd)

- * Fallow or bare ground
- * Crops other than small grains
- * Physical isolation such as road ditches, farmsteads, fence rows, wind breaks, etc.

OR

2) Destruction of the wheat trial prior to flowering.

When the field trial is located on a privately-owned farm, the responsible researcher must inform the owner of the farm as to the nature of the experiment and the need to maintain these plants and seed separately from any other plant material that is not part of the trial. The cooperator and/or owner should be instructed as to the need to frequently observe the plots for any signs of crop damage or vandalism and immediately report any such acts to Monsanto.

Inadvertent Mixing of Materials in Environmental Releases

Inadvertent mixing of regulated material and non-regulated wheat should be avoided. Inadvertent mixing may be prevented by planting each regulated article in a defined area with an unplanted alley between it and any other material. The width of this alley will vary depending on the method of harvesting and other operations. For machine harvesting, the alley should be wide enough to allow for machine movement without mechanical mixing. **All machinery (planting, maintenance, and harvesting) that may retain viable plant material should be cleaned after use in the regulated field, and before moving the equipment out of the regulated field. This will ensure that any regulated material retained by machinery will remain in the regulated field.**

For all plantings, identity must be maintained by planting regulated plants in distinct plots. Clearly stake out the plot, including border rows with easily identifiable markers (for example, metal or wooden stakes). It should remain clearly identified for the duration of the volunteer monitoring period. The use of stakes or markers to define the area where the regulated plants are grown will help in identifying volunteers for later elimination.

Devitalization

In a contained facility, seed and other material capable of natural propagation should be devitalized before leaving the contained facilities and/or placed in suitable containers prior to being shipped to another facility (see "Shipping") to prevent accidental release in the environment. Suitable means of devitalization at contained facilities include the use of:

- * dry or steam heat
- * physical grinding
- * chemicals or
- * composting (at a location that can be monitored until devitalization occurs).

In an environmental release, plant material or seed may also be disposed of according to the conditions of your field project plan/protocol. For example, send seed back to the origination point, or to post-harvest location(s) in appropriate containers, bury or disk in the field plot, etc. Final disposition and devitalization, after harvest, may also be achieved by one of the following methods: hand weeding, grinding, incineration, chemical application or mechanical cultivation. In some cases, the remaining vegetative material in the field can be incorporated into the soil and left to natural devitalization by the elements. These requirements apply to the entire plot area, including the border rows.

Post-Harvest Monitoring for Volunteer Plants

The area (plot area including border rows) must be monitored for volunteers and all volunteers must be destroyed. Volunteers can be minimized by growing regulated material in defined areas in the field and by utilizing adequate termination protocols. **Wheat trials destroyed before flowering still require volunteer monitoring due to seed dormancy.**

After field trial completion, plots will be monitored for a period of twenty-four (24) months. If volunteers are still present at the last monitoring time, continue to monitor for volunteers and contact your compliance specialist.

Volunteers will be removed prior to seed set or flowering. Methods that can be used to eliminate volunteers include tillage, herbicide application, and hand weeding.

Arrangements must be made to allow access to the land for the volunteer-monitoring period.

Replanting of the field trial plot during the next field season must be done in such a manner as to allow for appropriate volunteer monitoring. Options for replanting the test and border row areas are:

- * Leave the site fallow and control any volunteer plants.
- * Plant to another appropriate rotational crop which would allow the clear identification and control of volunteer wheat plants.
- * Plant to regulated wheat and follow the requirements for that regulated wheat material.
- * If planting to a non-regulated crop of the same species, the rules for field testing a regulated field trial must be followed.

The following requirements must be met in continuous nursery situations, as in Hawaii and Puerto Rico:

- * **The field should remain fallow for a minimum of 30 days or an additional time period mandated by the State Department of Agriculture. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Then the volunteer wheat should be destroyed. Any additional requirements mandated by the State Department of Agriculture must be met.**

Compliance

The site responsible researcher must:

- 1) Comply with all applicable requirements set forth in this Crop Performance Standard.
- 2) Have the Crop Performance Standard available during a USDA inspection.
- 3) Notify the Monsanto compliance specialist within 24 hours of any compliance violation or unintentional release of regulated material.

If a compliance violation or unintentional release occurs, stabilize the situation first, then gather information and call the compliance specialist. The proper agency authorities will then be contacted by the Monsanto Compliance Team, as required.

Examples of compliance violations:

- * Allowing regulated material to enter commerce
- * Failure to adhere to isolation requirements, as described in Crop Performance Standard
- * Failure to have the Crop Performance Standard available during a USDA inspection

Wheat Performance Standards (Cont'd)

- * Feeding of regulated plant material to livestock
- * Failure to monitor for volunteers
- * Planting without an approved notification
- * Conducting trial activities outside of the approved dates of the notification
- * Moving planting or harvesting equipment from the plot site before cleaning
- * Mixing regulated plant material with non-regulated plant material
- * Planting at an unapproved site or in an unapproved state
- * Planting more acreage than approved on the notification
- * Shipping to an unapproved location or to an unapproved state
- * Loss of seed by shipping company, applicant or designated representative
- * Movement of seed or regulated plant material outside the test area by natural causes (floods, tornadoes, etc.)

CONFIDENTIAL

2003 Wheat Field Test Report
USDA #03-052-28n **Monsanto #2003-206XRAB**

May 11, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147315700	Fergus	MT
2147315696	Teton	MT
2147316016	Gallatin	MT
2147308221	Gallatin	MT

Fergus County/MT (2147315700)

(b) (4)

(b) (4)

Teton County/MT (2147315696)

(b) (4)

(b) (4)

Gallatin County/MT (2147316016)

(b) (4)

(b) (4)

Gallatin County/MT (2147308221)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2003 Wheat Field Test Report
USDA #03-052-28n Monsanto #2003-206XRAB

May 11, 2004

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147315700	Fergus	MT
2147315696	Teton	MT
2147316016	Gallatin	MT
2147308221	Gallatin	MT

Fergus County/MT (2147315700)

Planting Date: 04/28/2003

Harvest Date: 08/06/2003

Destruct Date: 09/26/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Teton County/MT (2147315696)

Planting Date: 05/12/2003

Harvest Date: 08/18/2003

Destruct Date: 08/28/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Gallatin County/MT (2147316016)

Planting Date: 05/09/2003

Harvest Date: 08/15/2003

Destruct Date: 11/13/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Gallatin County/MT (2147308221)

Planting Date: 05/21/2003

Harvest Date: 08/28/2003

Destruct Date: 09/24/2003

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]